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Yaari

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(54) **LAPAROSCOPIC WORKSPACE DEVICE**

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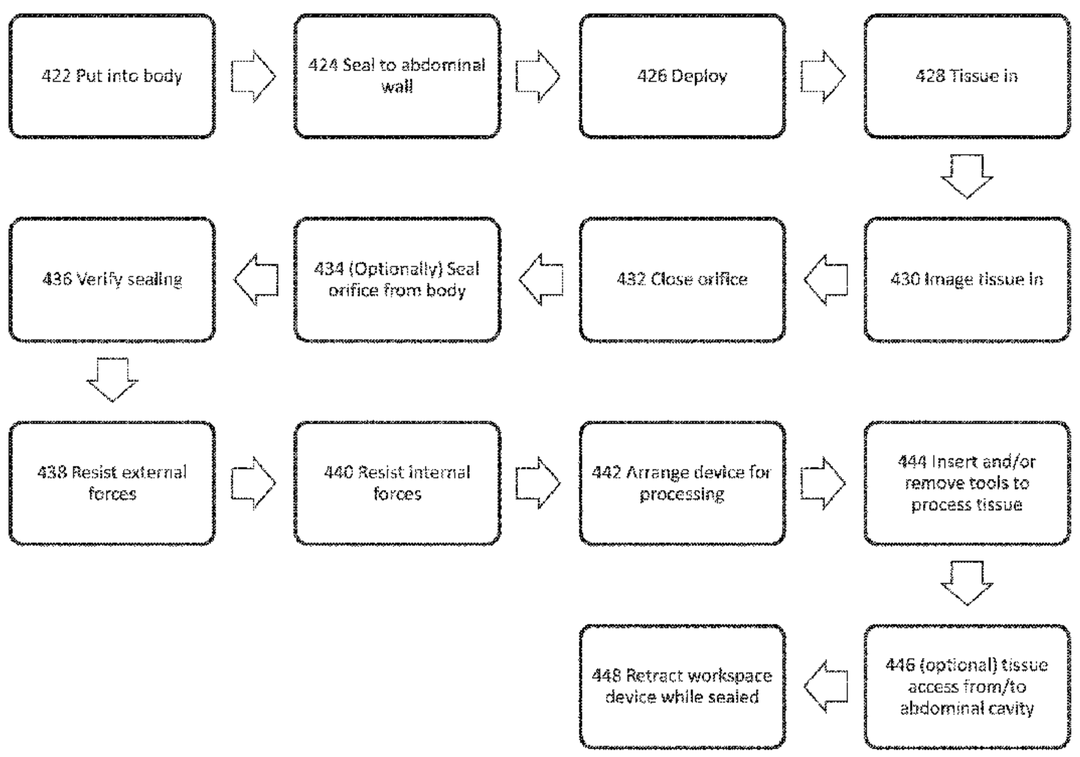
(57) **ABSTRACT**

A workspace device including (a) a body having a wall defining an internal volume, collapsible to fit through a laparoscopic passageway in an abdominal wall to an abdominal cavity and expand therein; (b) a first opening defined in said body; (c) a tool channel contiguous with said first opening and extending from said body and configured to remain, at least in part, outside of abdominal wall and sized to receive a laparoscopic tool therein therein; and (d) the body defining an orifice configured to lie in said abdominal cavity when said body is inserted therein, said orifice sized to receive tissue with a minimal cross-sectional area that is twice a minimal cross-sectional area of said first opening, thereby defining a workspace volume to process said tissue in said cavity while said body is not collapsed, using a tool inserted through said first opening.

19 Claims, 43 Drawing Sheets



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See application file for complete search history.

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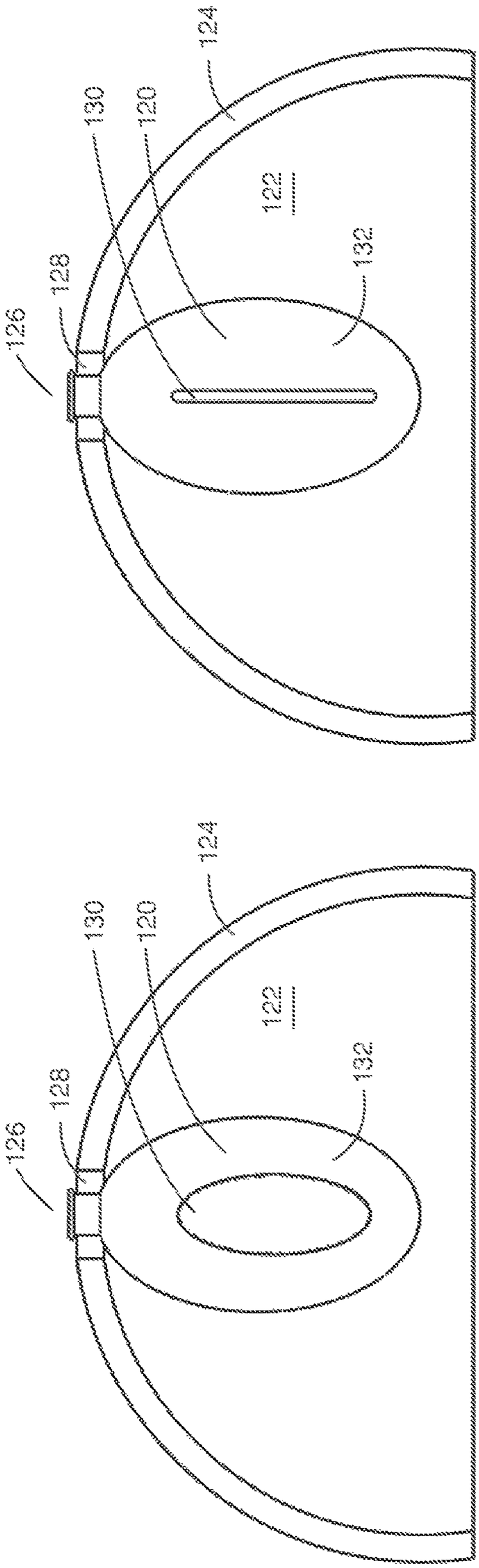


FIG. 1B

FIG. 1A

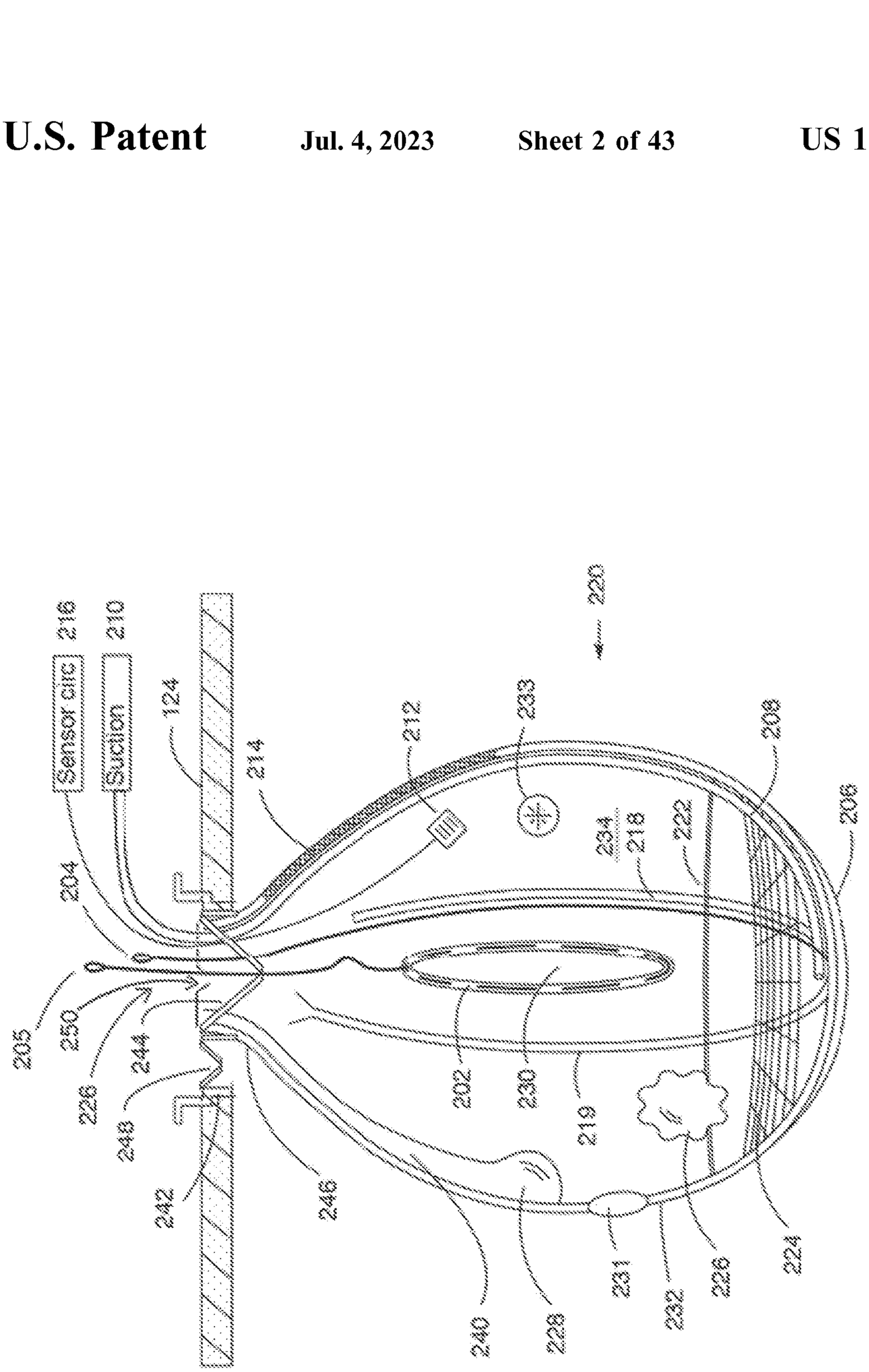

Sensor circ
Suction
216
210
124
214
212
232
220
208
204
234
218
222
206
205
250
244
226
202
230
219
248
242
246
231
232
226
224
240
228

FIG. 2

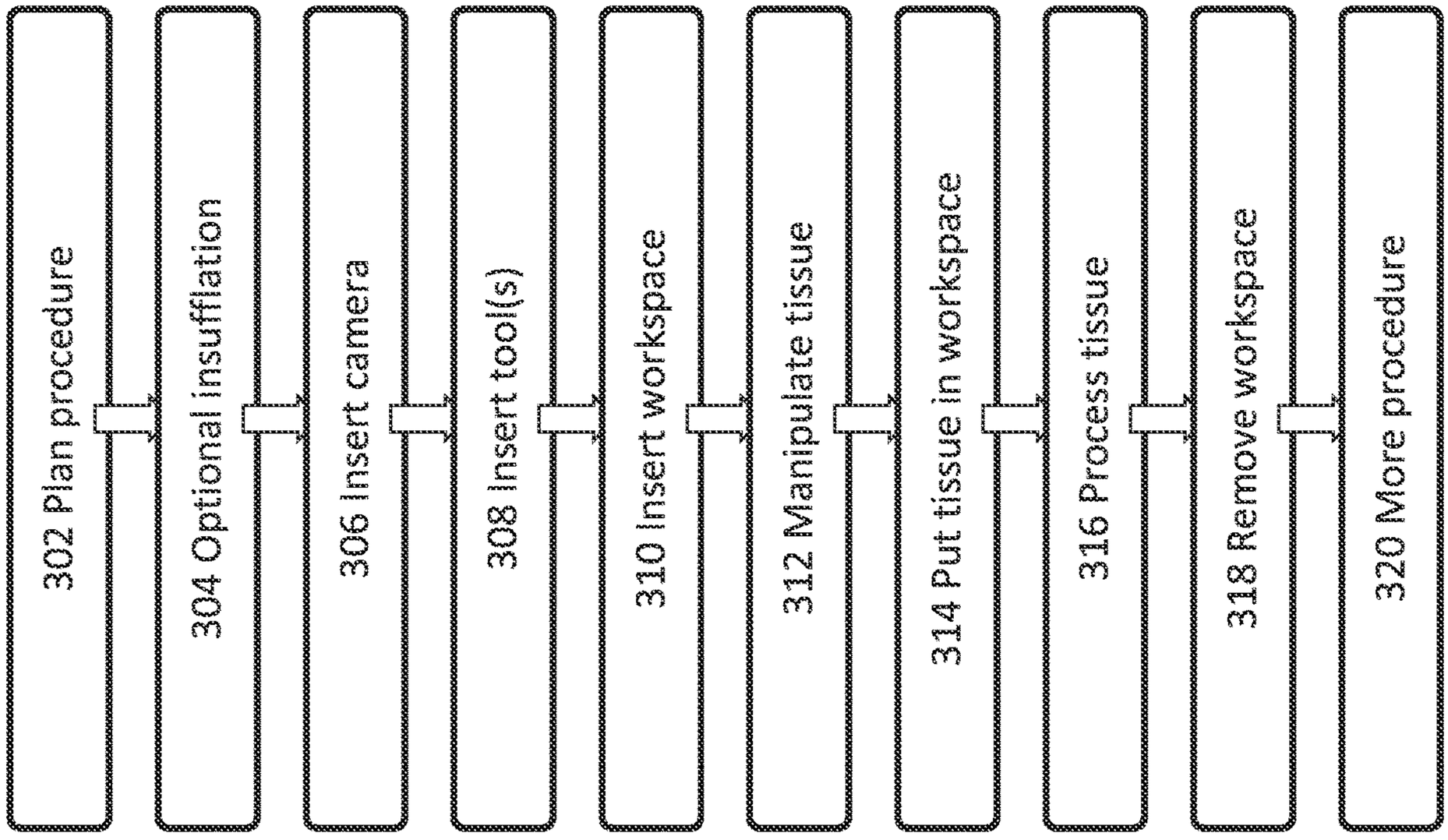

302 Plan procedure
304 Optional insufflation
306 Insert camera
308 Insert tool(s)
310 Insert workspace
312 Manipulate tissue
314 Put tissue in workspace
316 Process tissue
318 Remove workspace
320 More procedure

FIG. 3

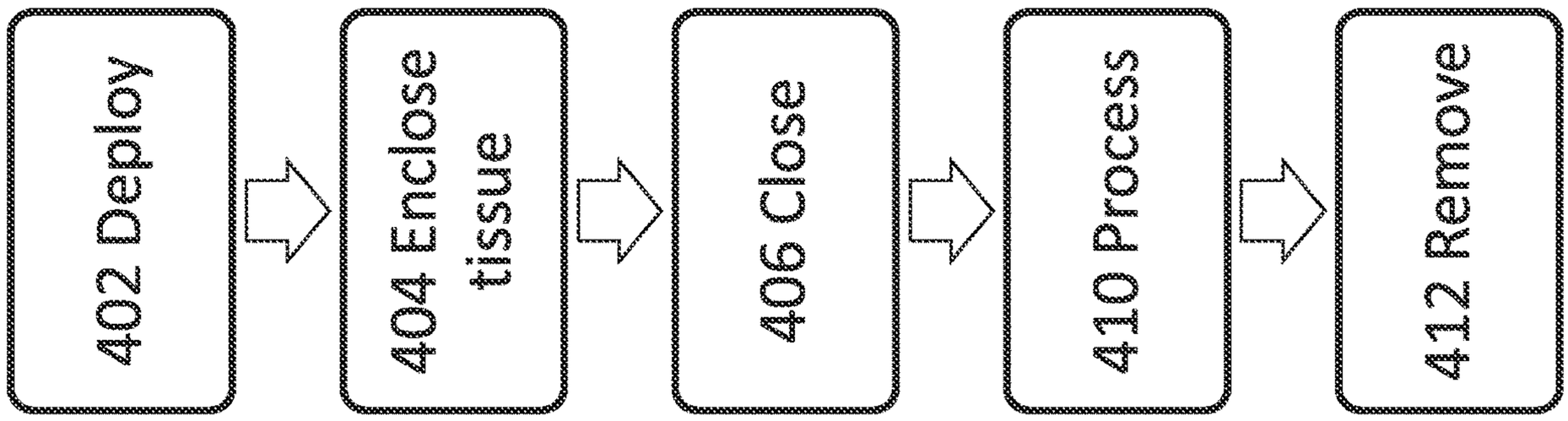

402 Deploy
404 Enclose tissue
406 Close
410 Process
412 Remove

FIG. 4A

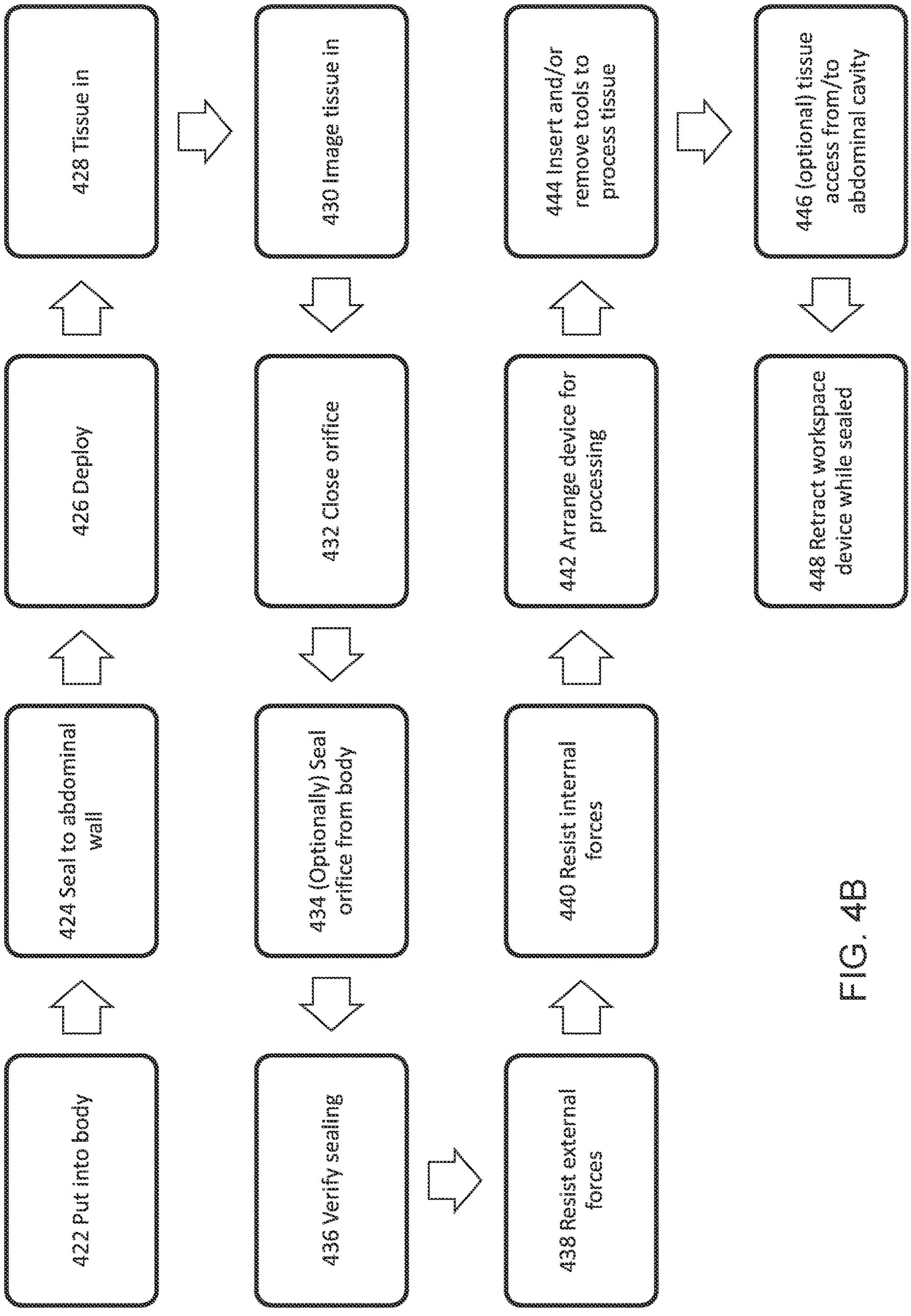

428 Tissue in
430 Image tissue in
444 Insert and/or remove tools to process tissue
446 (optional) tissue access from/to abdominal cavity
426 Deploy
432 Close orifice
442 Arrange device for processing
448 Retract workspace device while sealed
424 Seal to abdominal wall
434 (Optionally) Seal orifice from body
440 Resist internal forces
422 Put into body
436 Verify sealing
438 Resist external forces

FIG. 4B

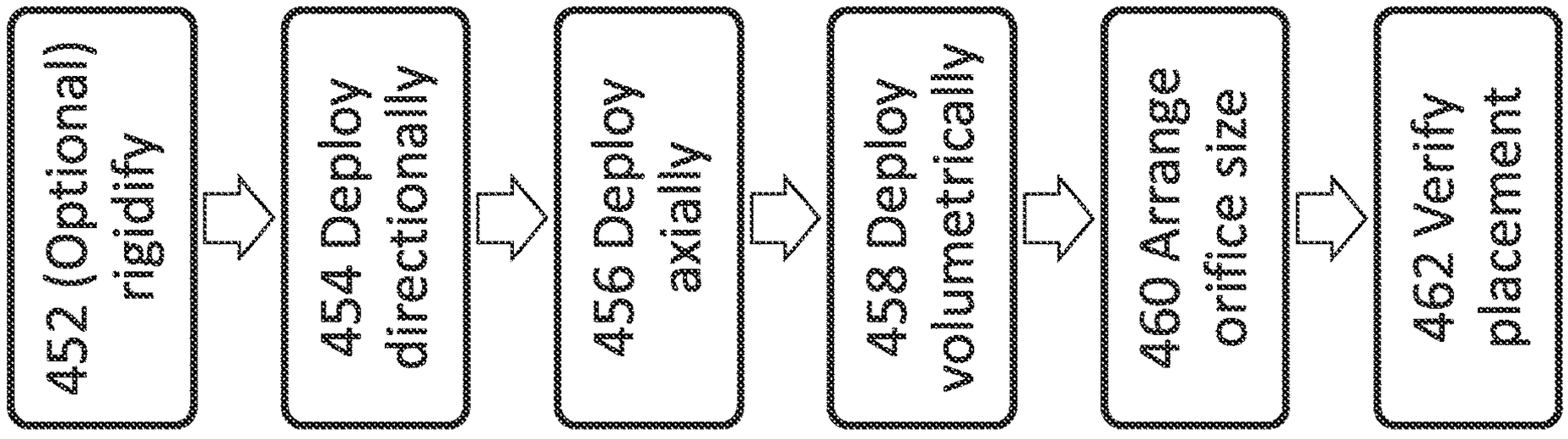

452 (Optional) rigidify
454 Deploy directionally
456 Deploy axially
458 Deploy volumetrically
460 Arrange orifice size
462 Verify placement

FIG. 4C

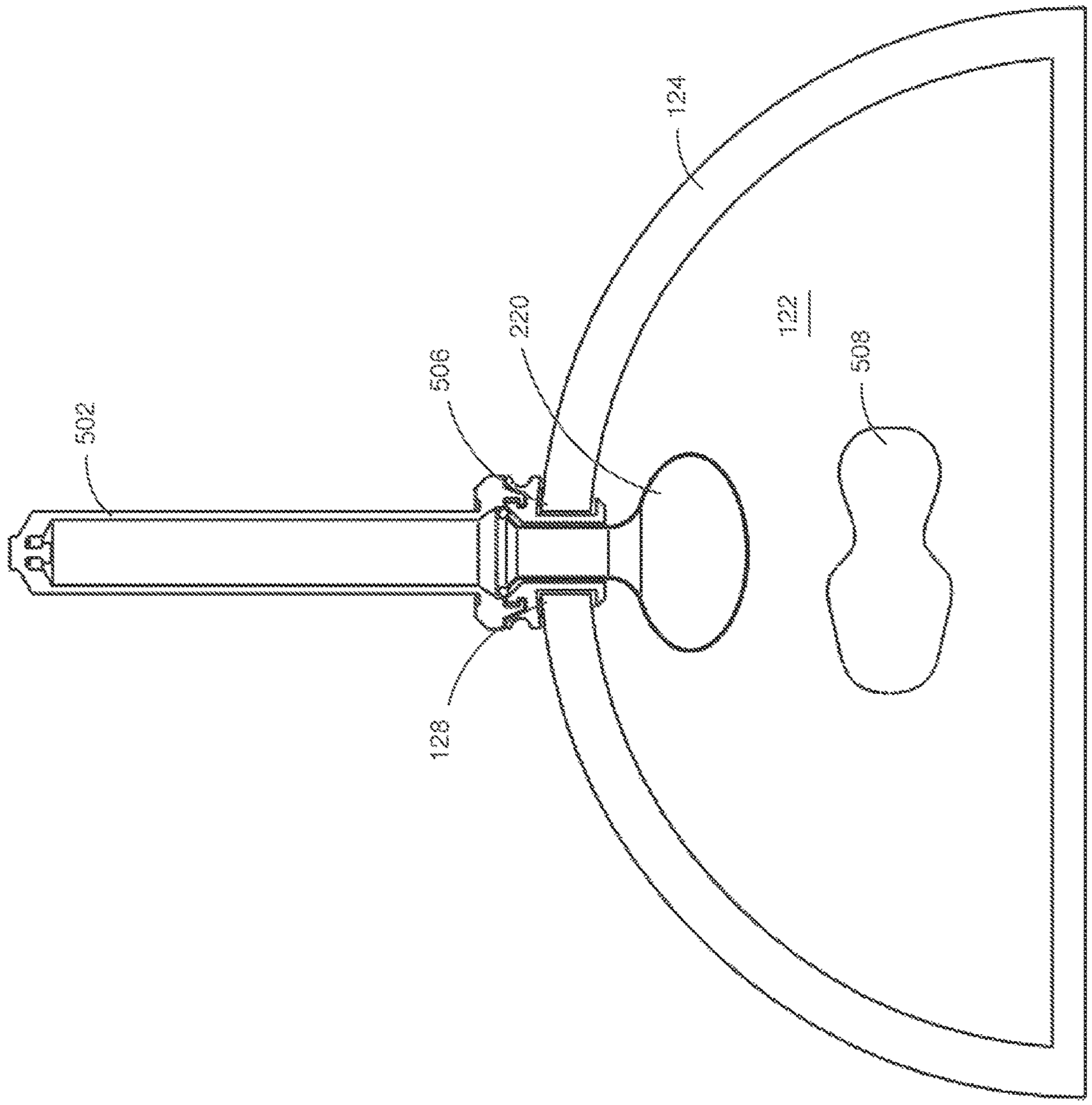


FIG. 5

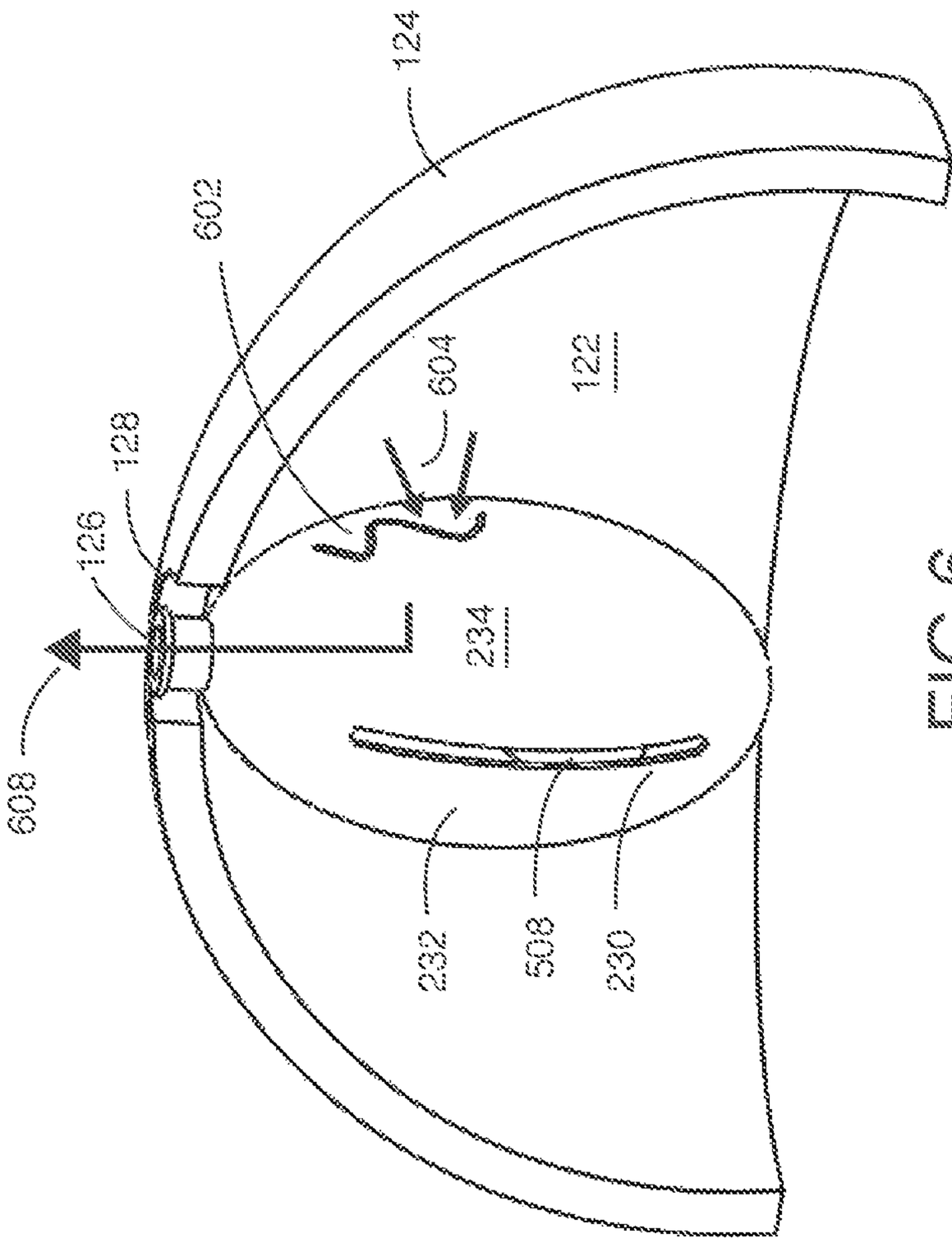


FIG. 6

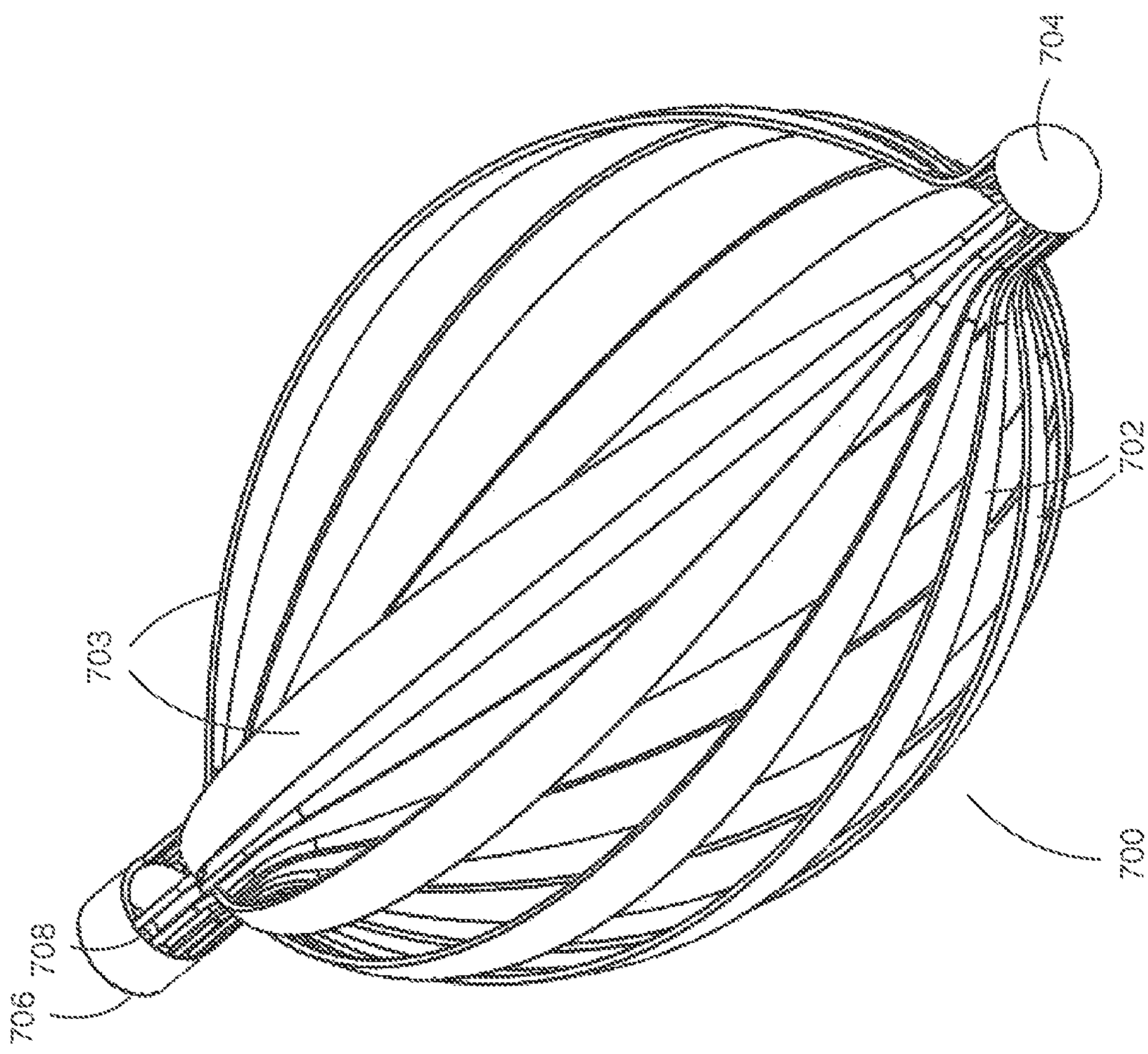


FIG. 7A

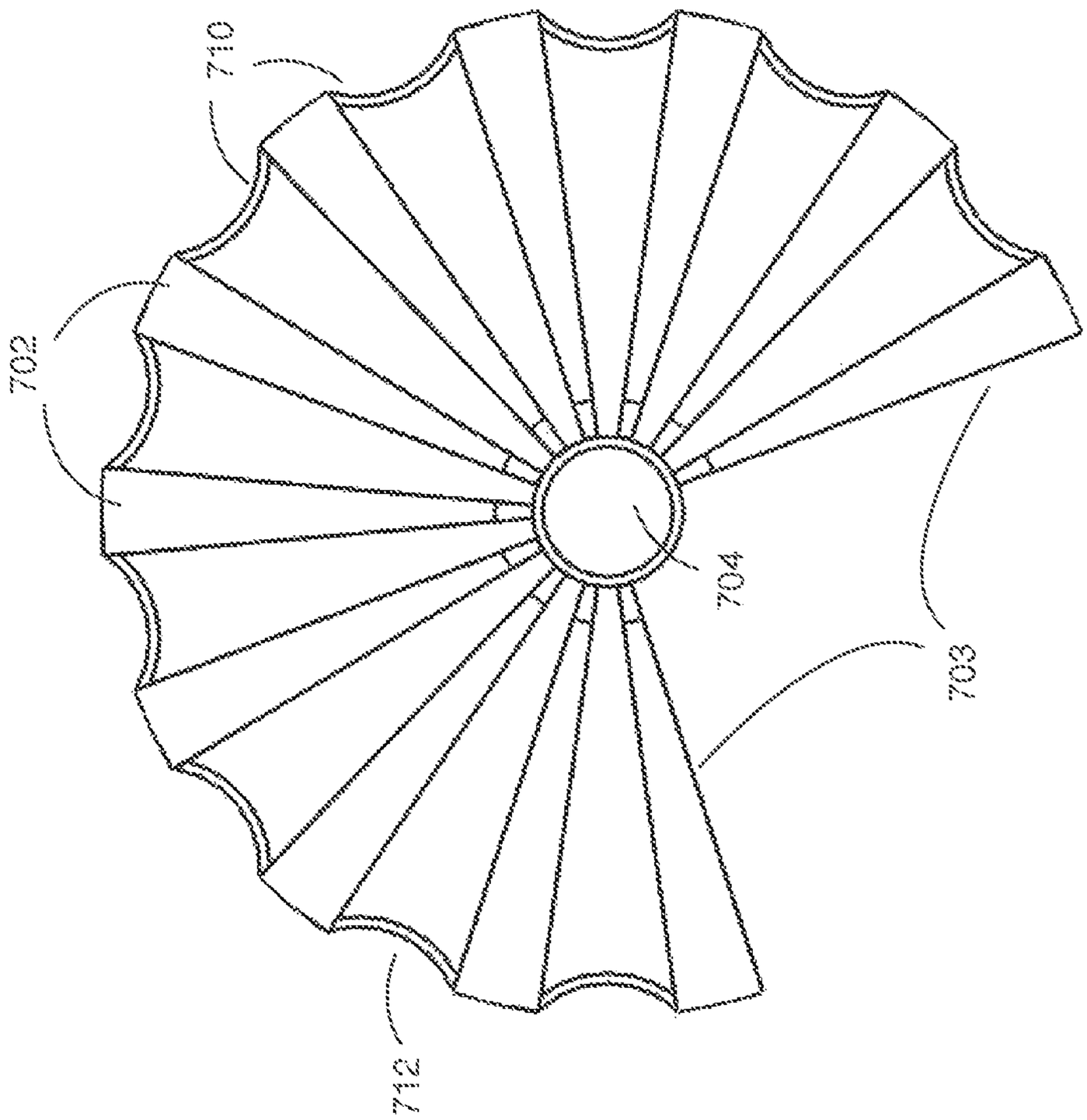


FIG. 7B

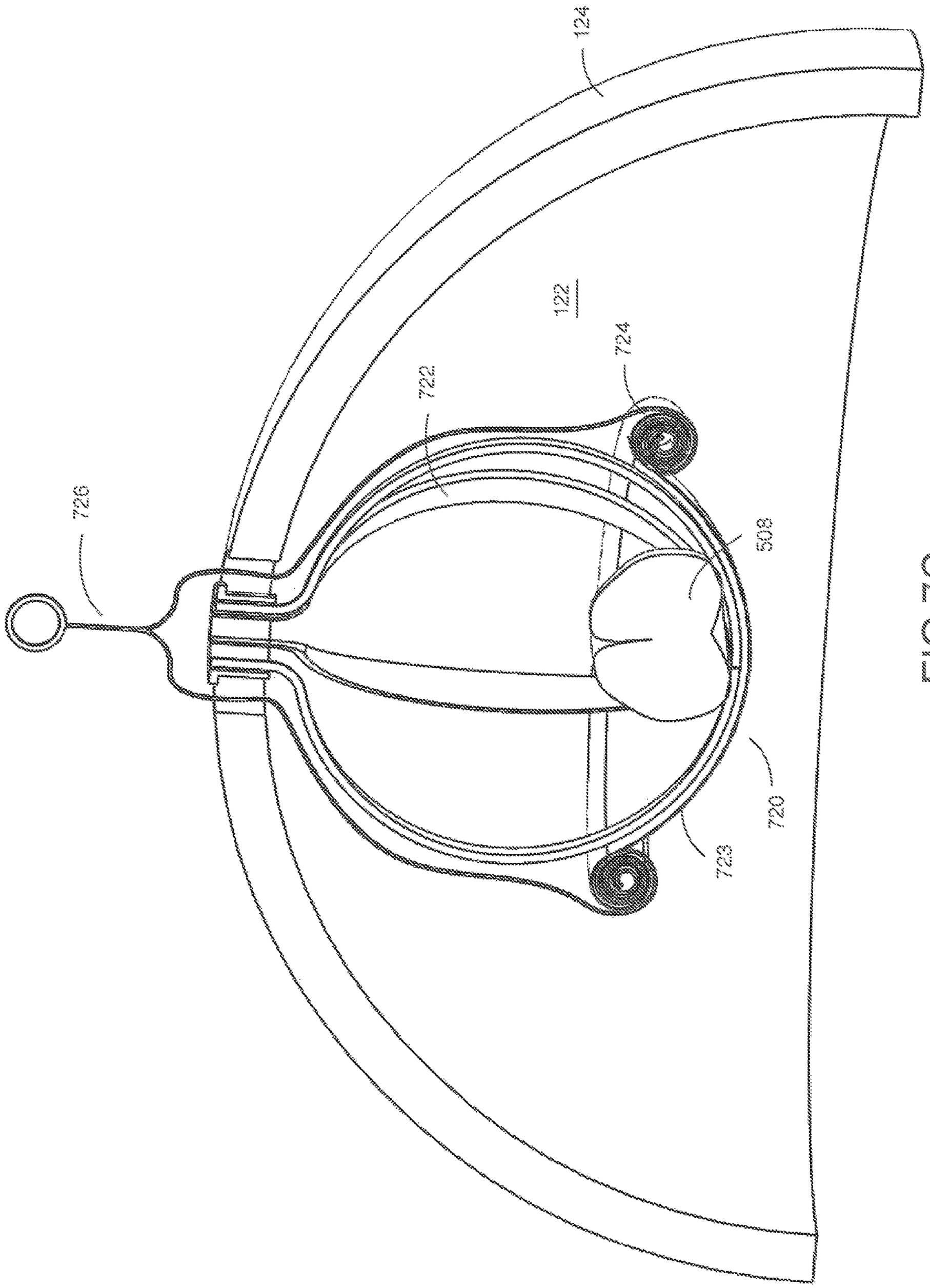


FIG.7C

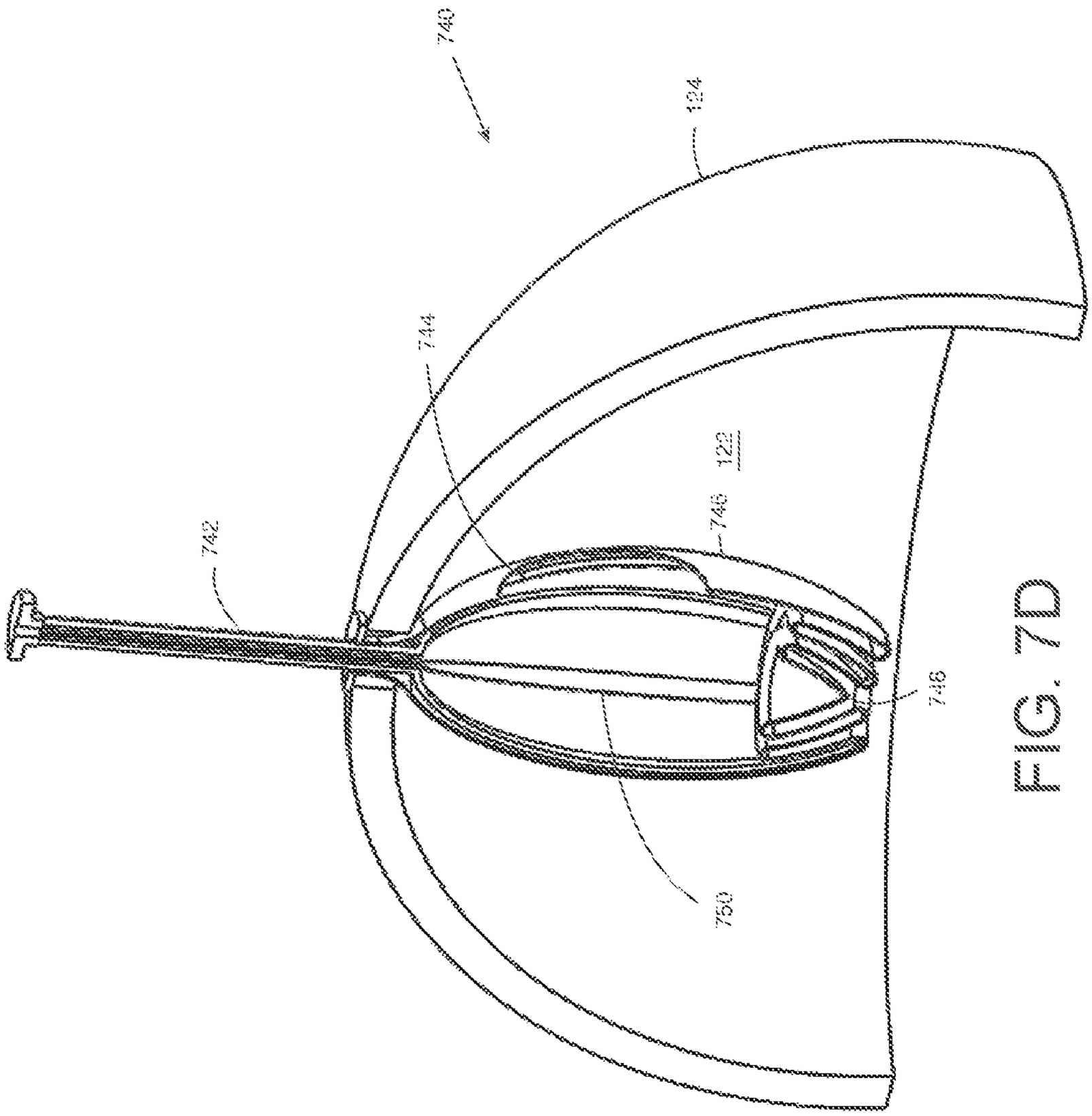


FIG. 7D

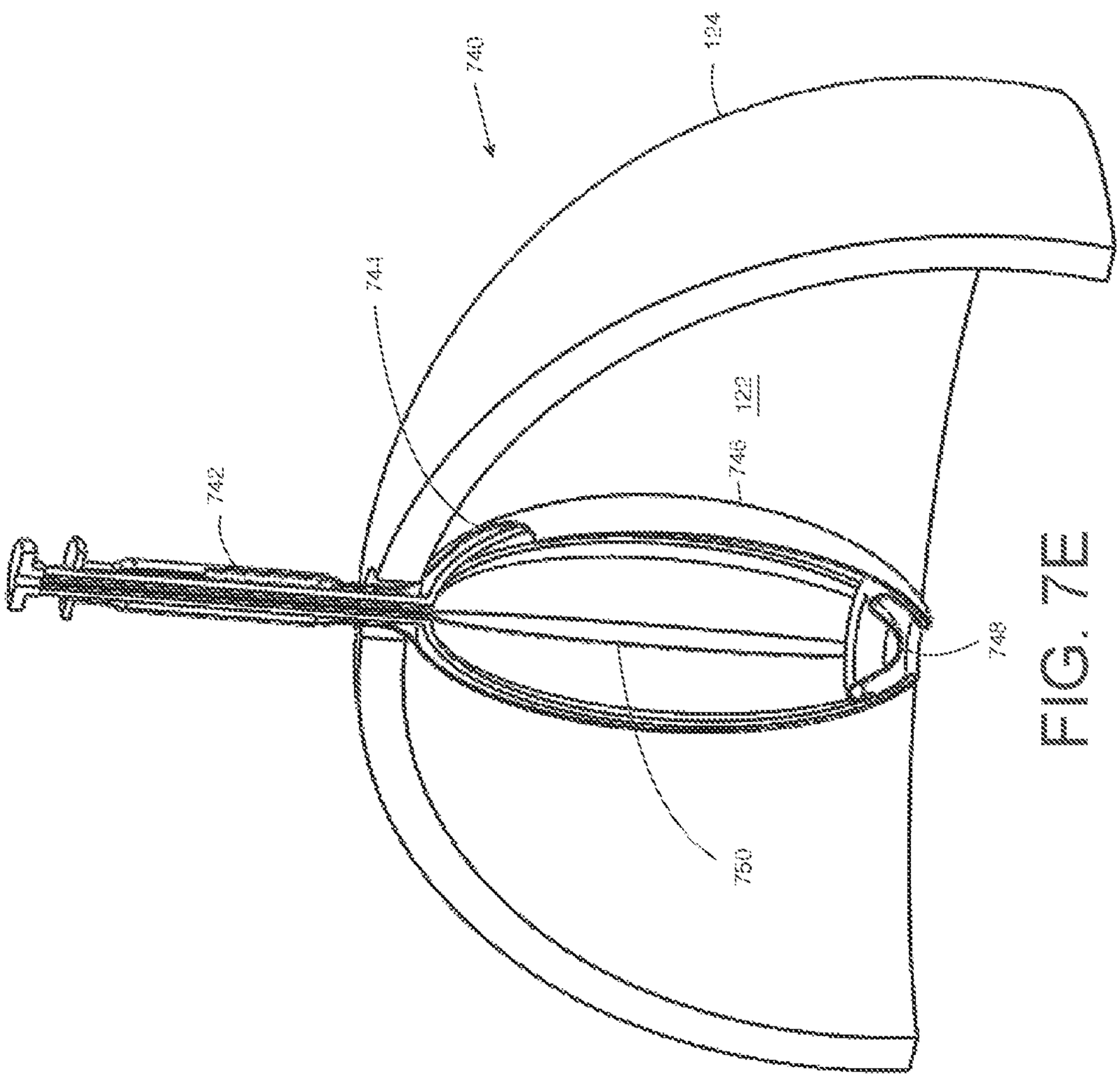


FIG. 7E

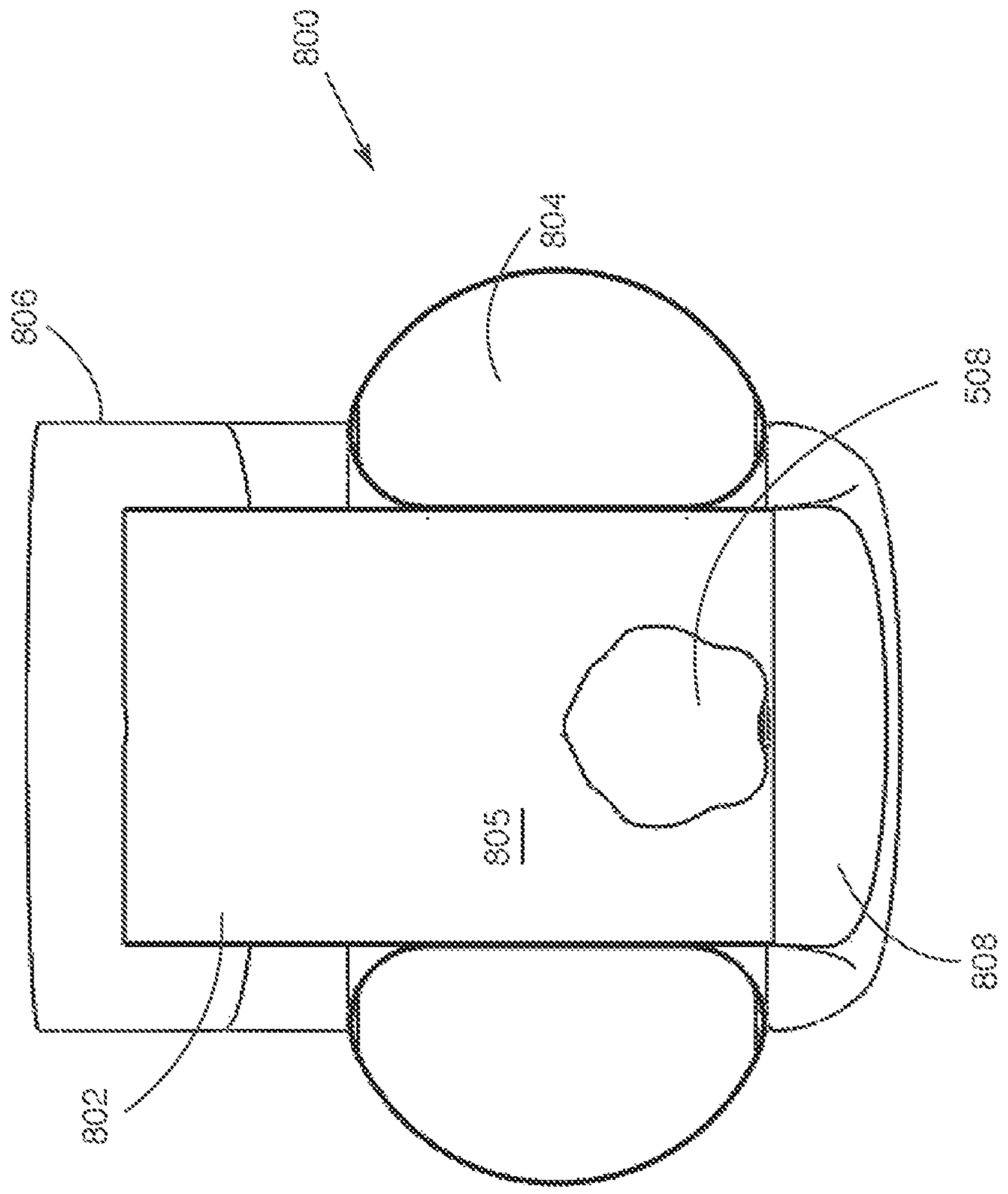
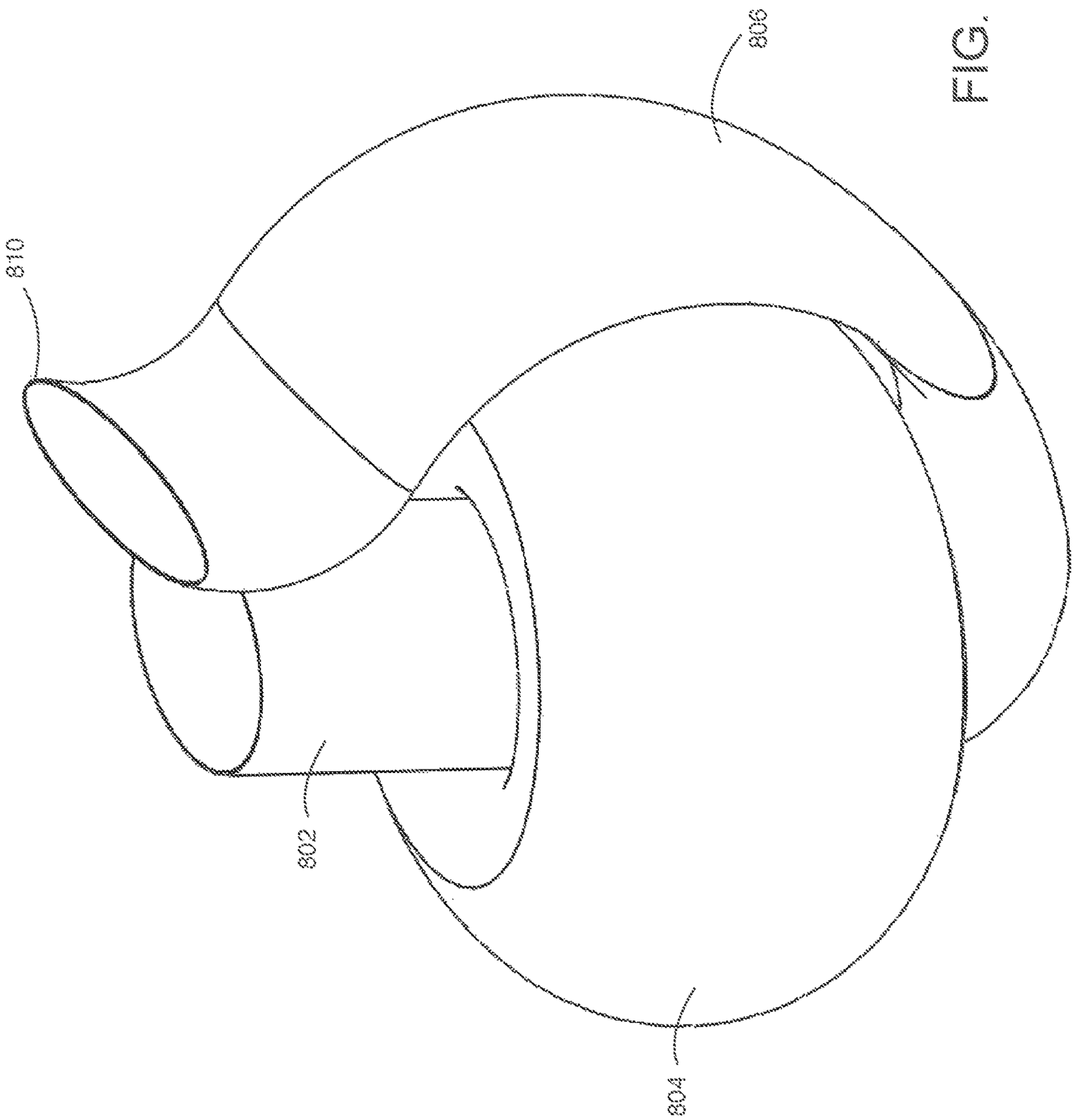


FIG. 8A

FIG. 8B



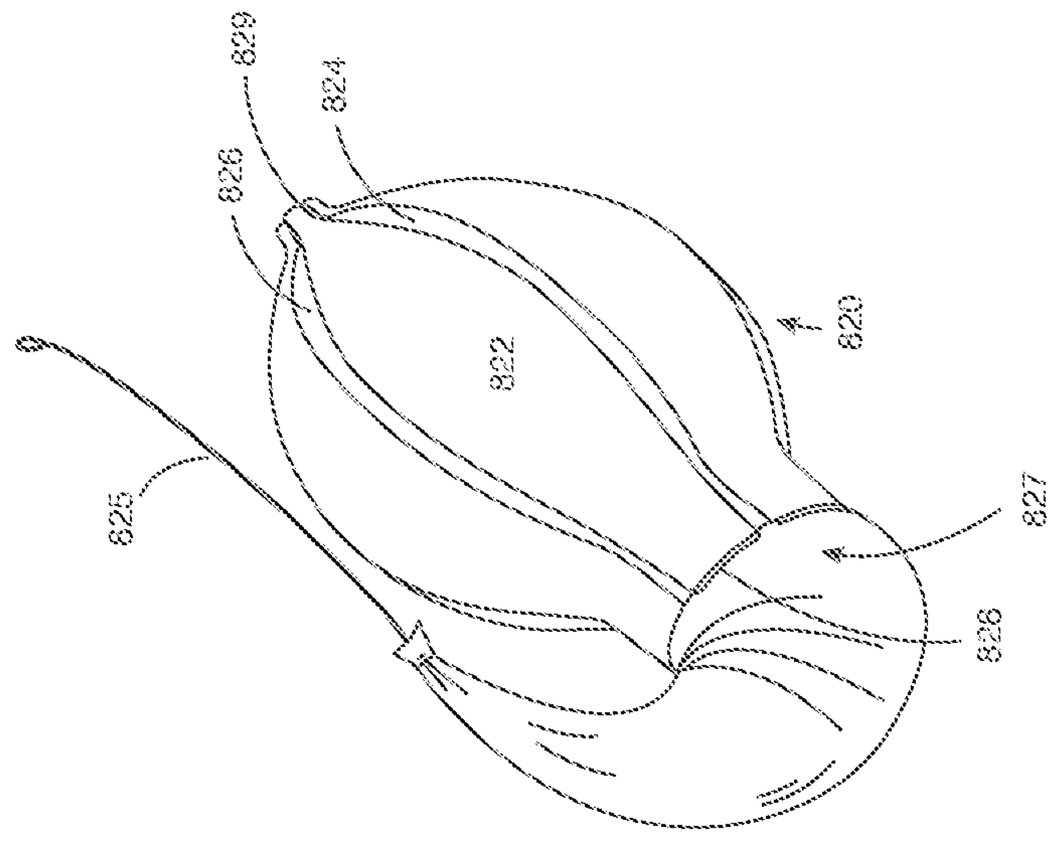


FIG. 8C

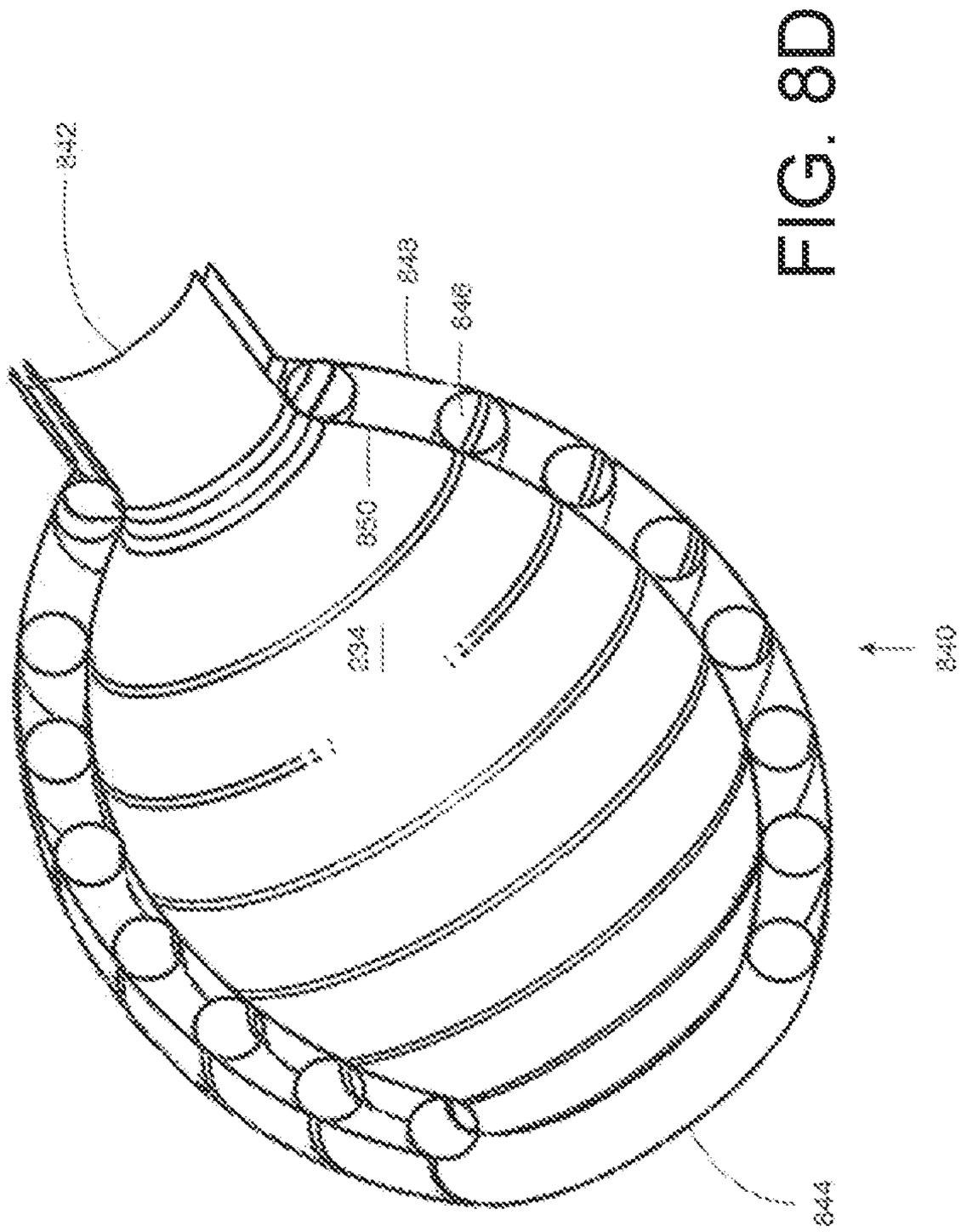


FIG. 8

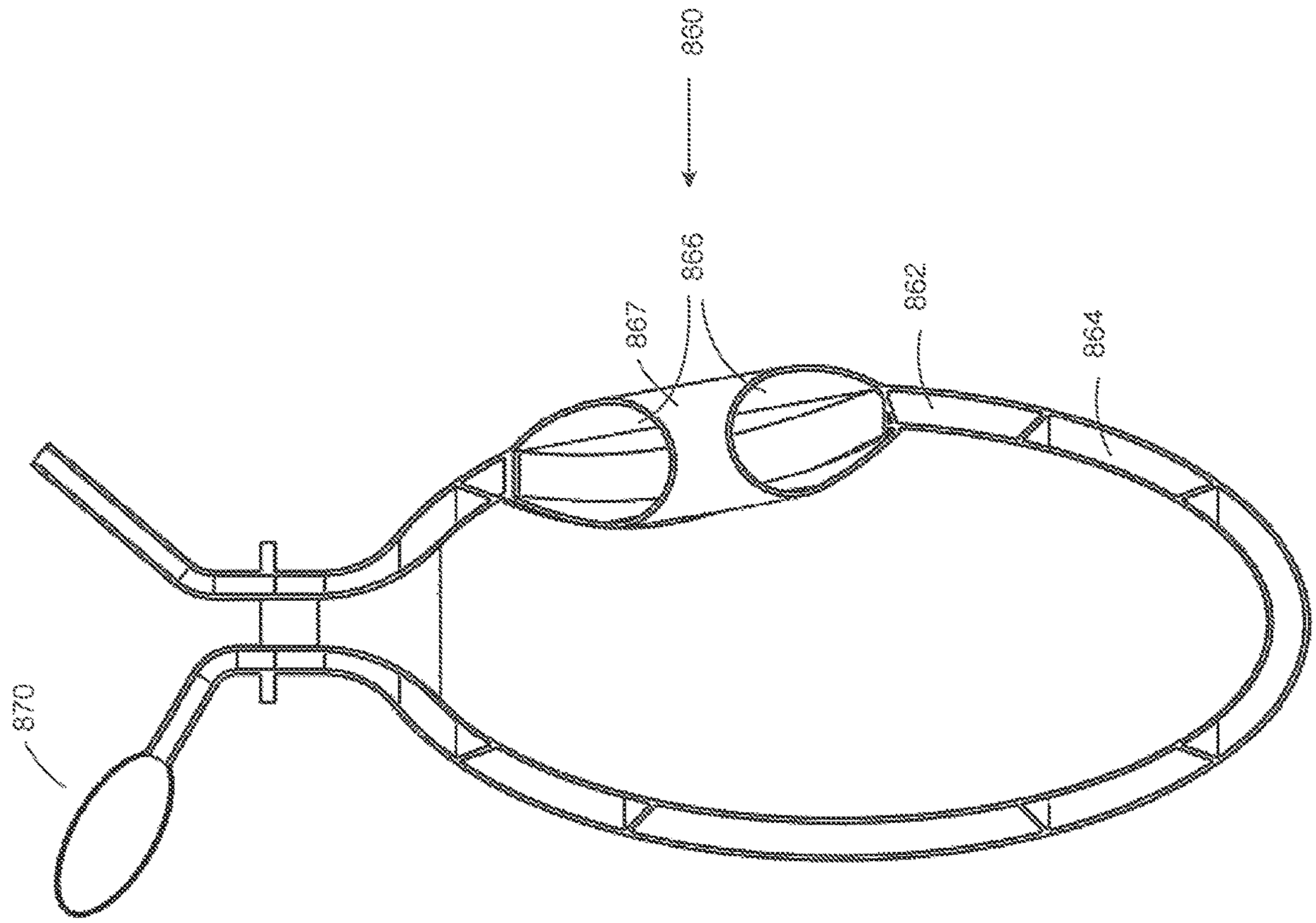


FIG. 8E

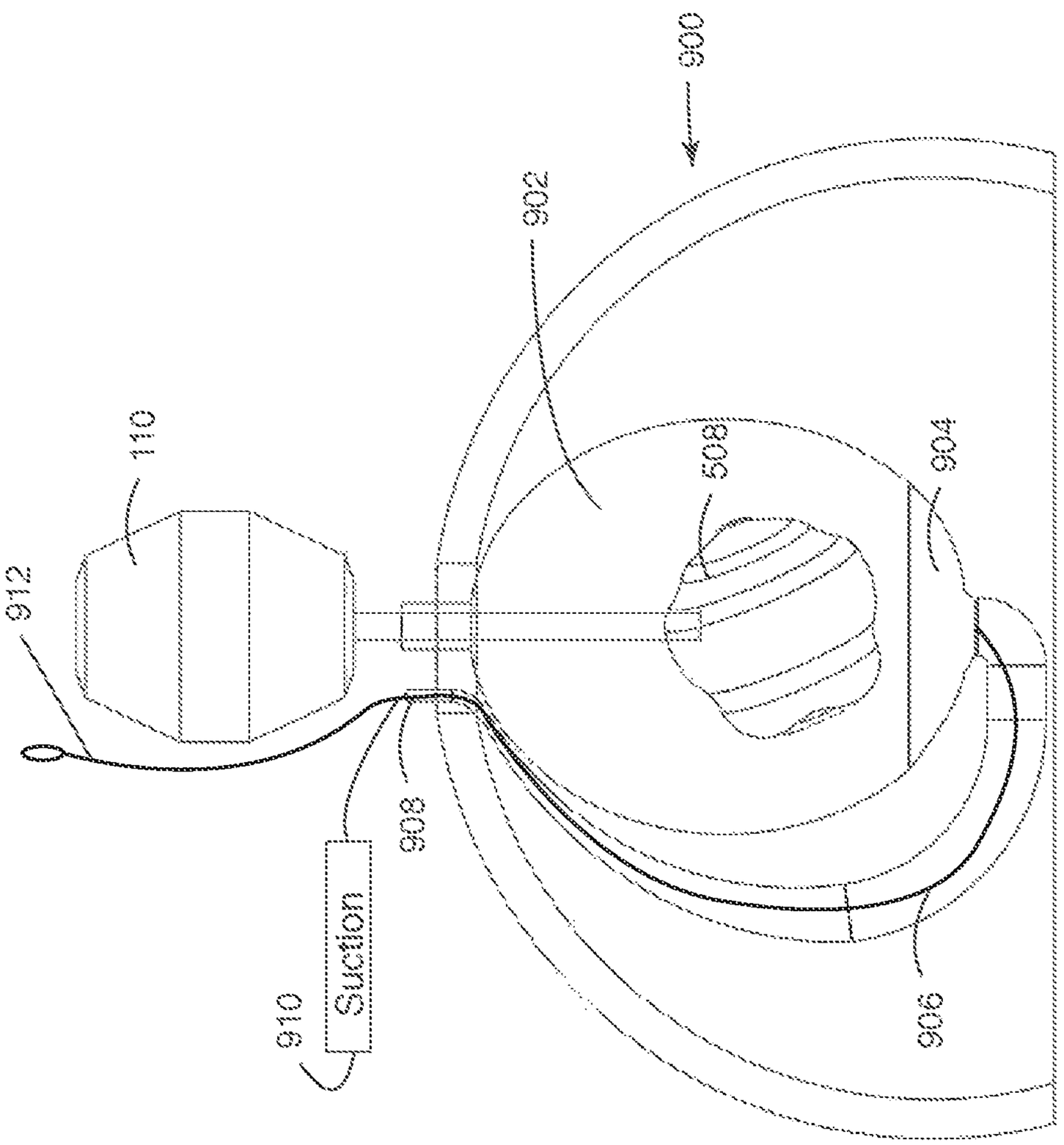


FIG. 9A

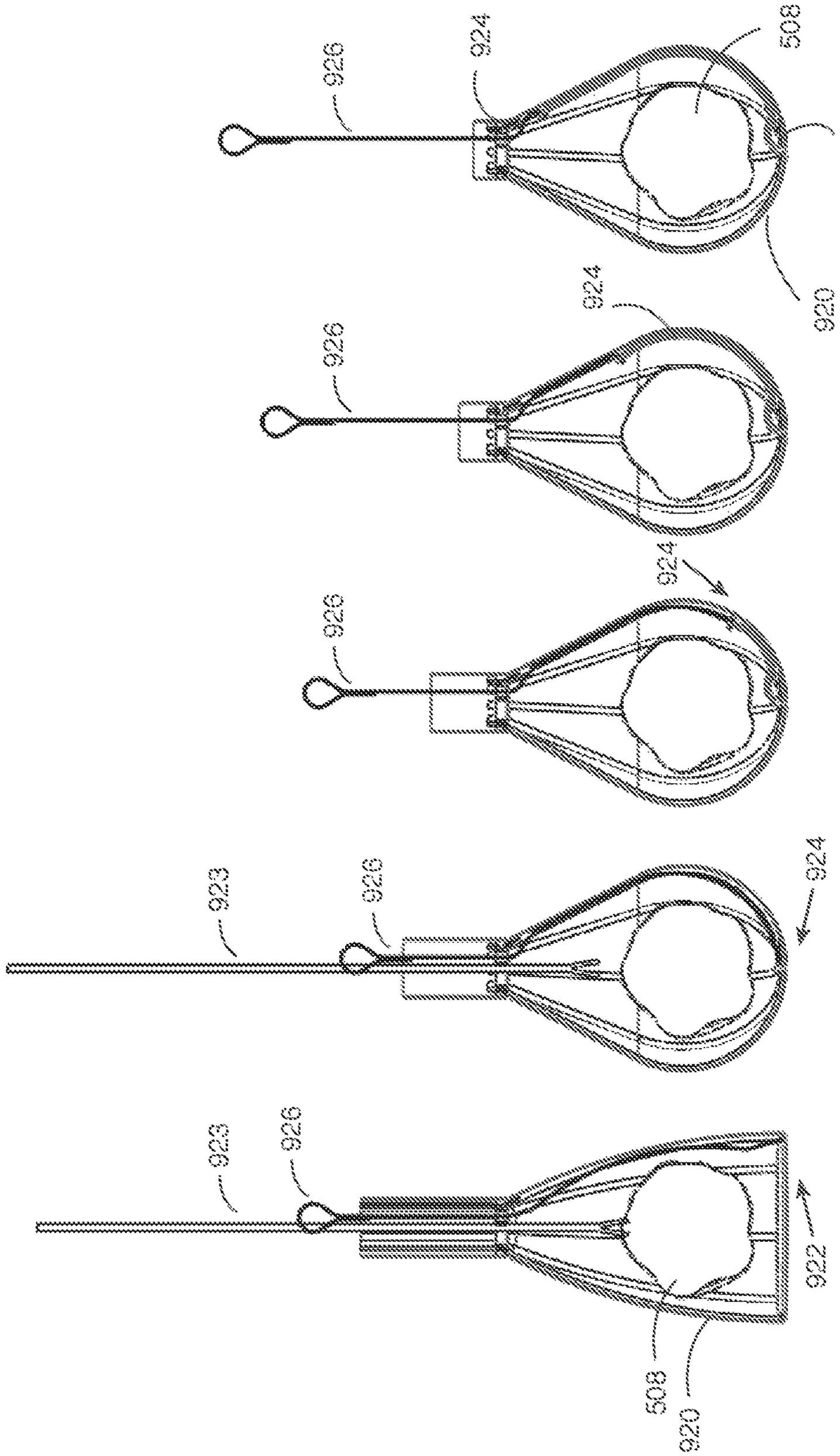


FIG. 9F FIG. 9D FIG. 9E

FIG. 9C FIG. 9B

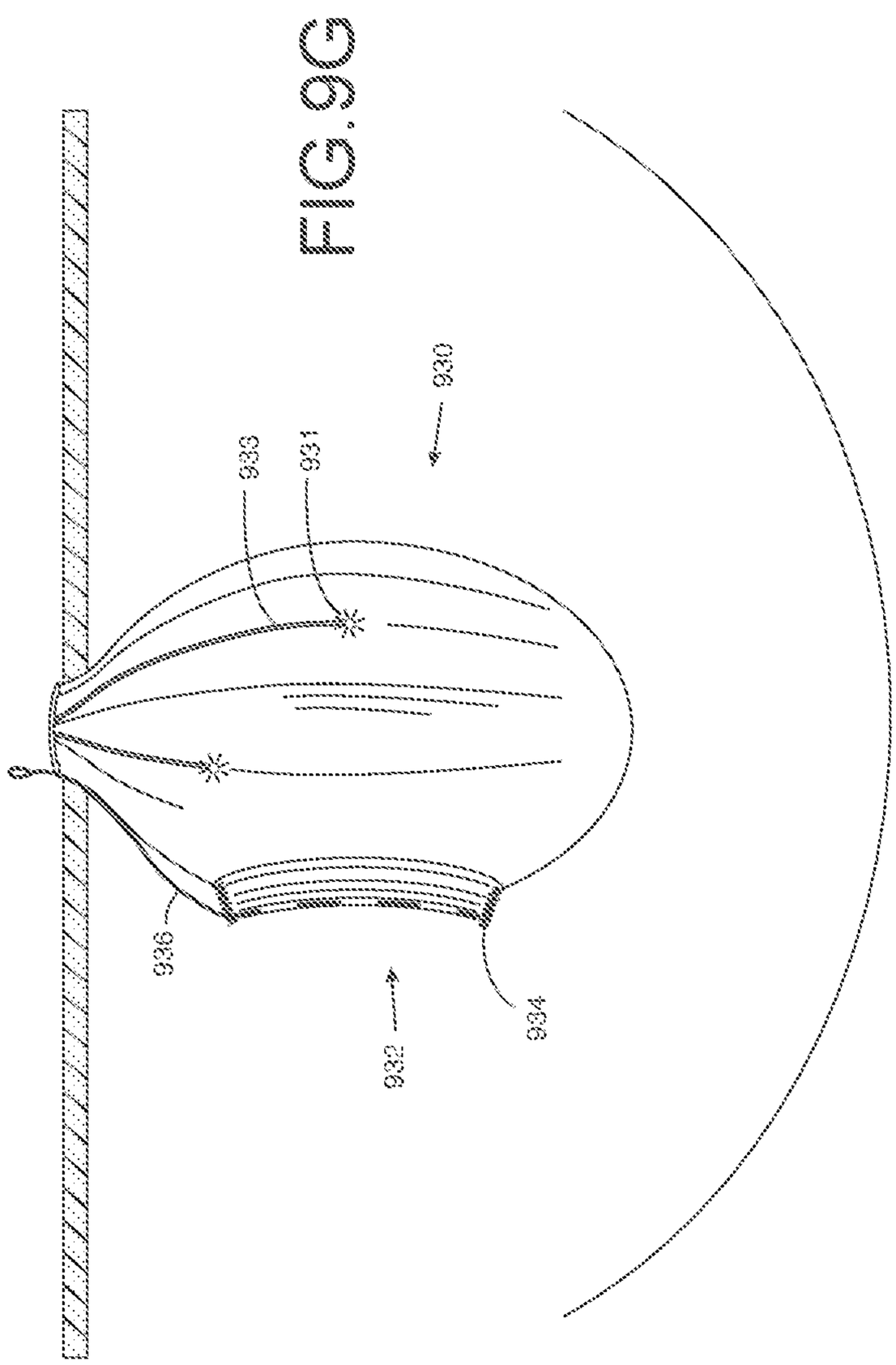


FIG. 9

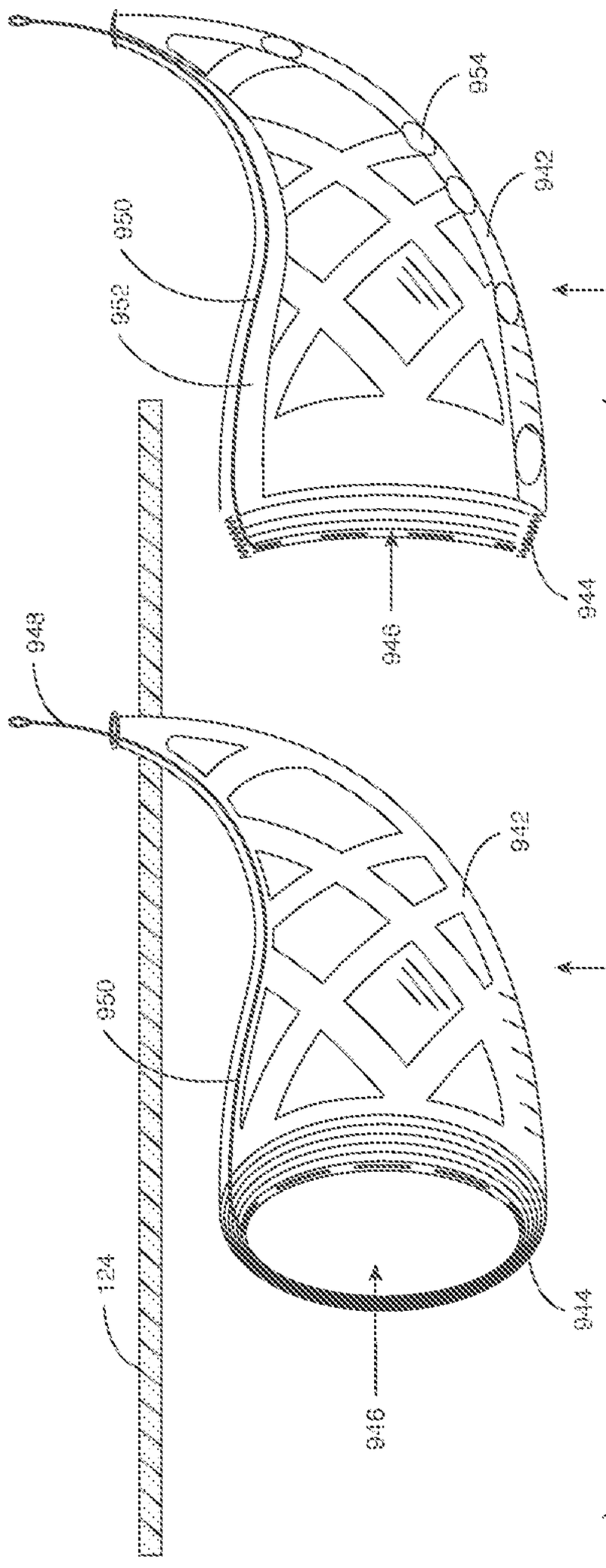
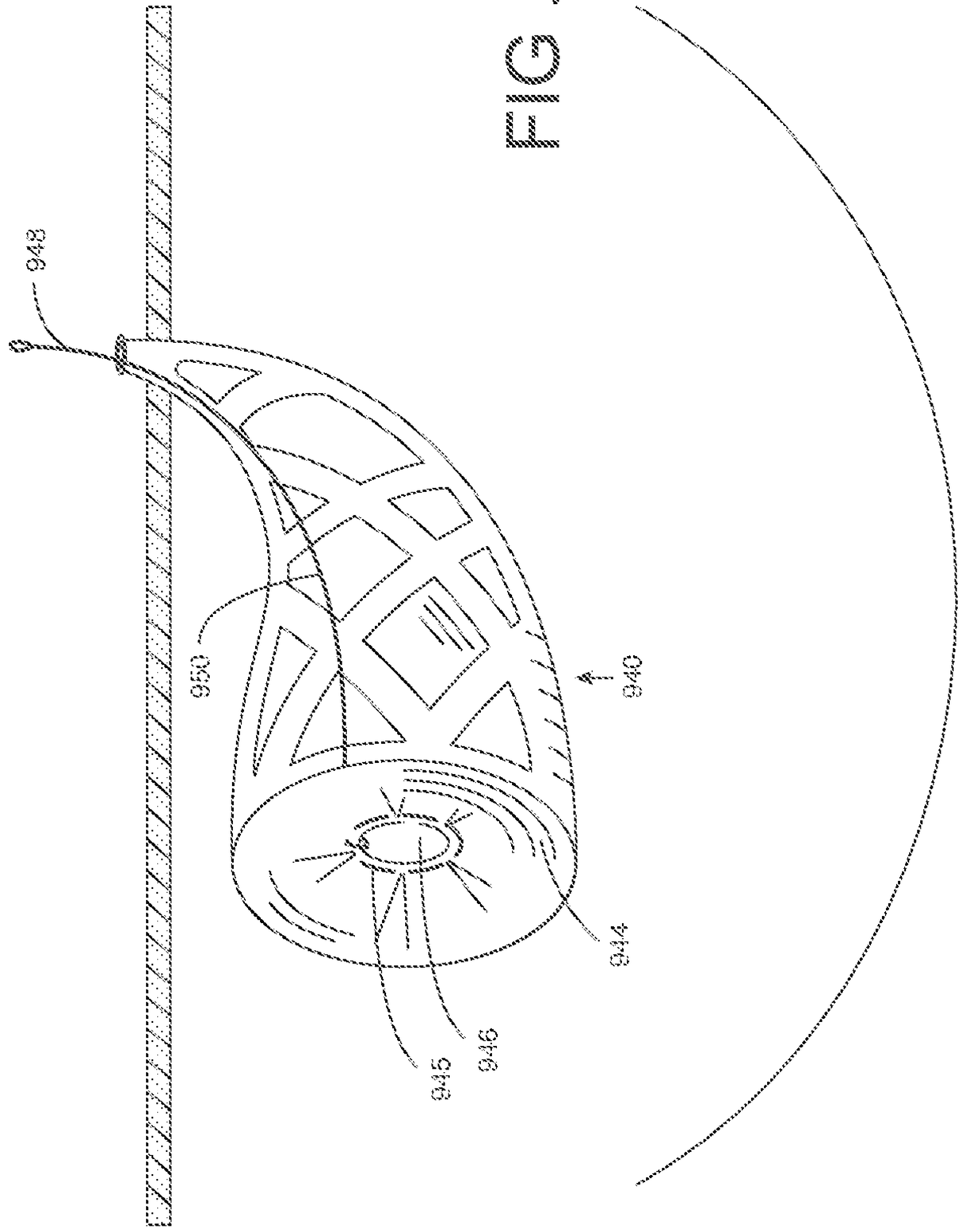


FIG. 9I

FIG. 9H

FIG. 9J



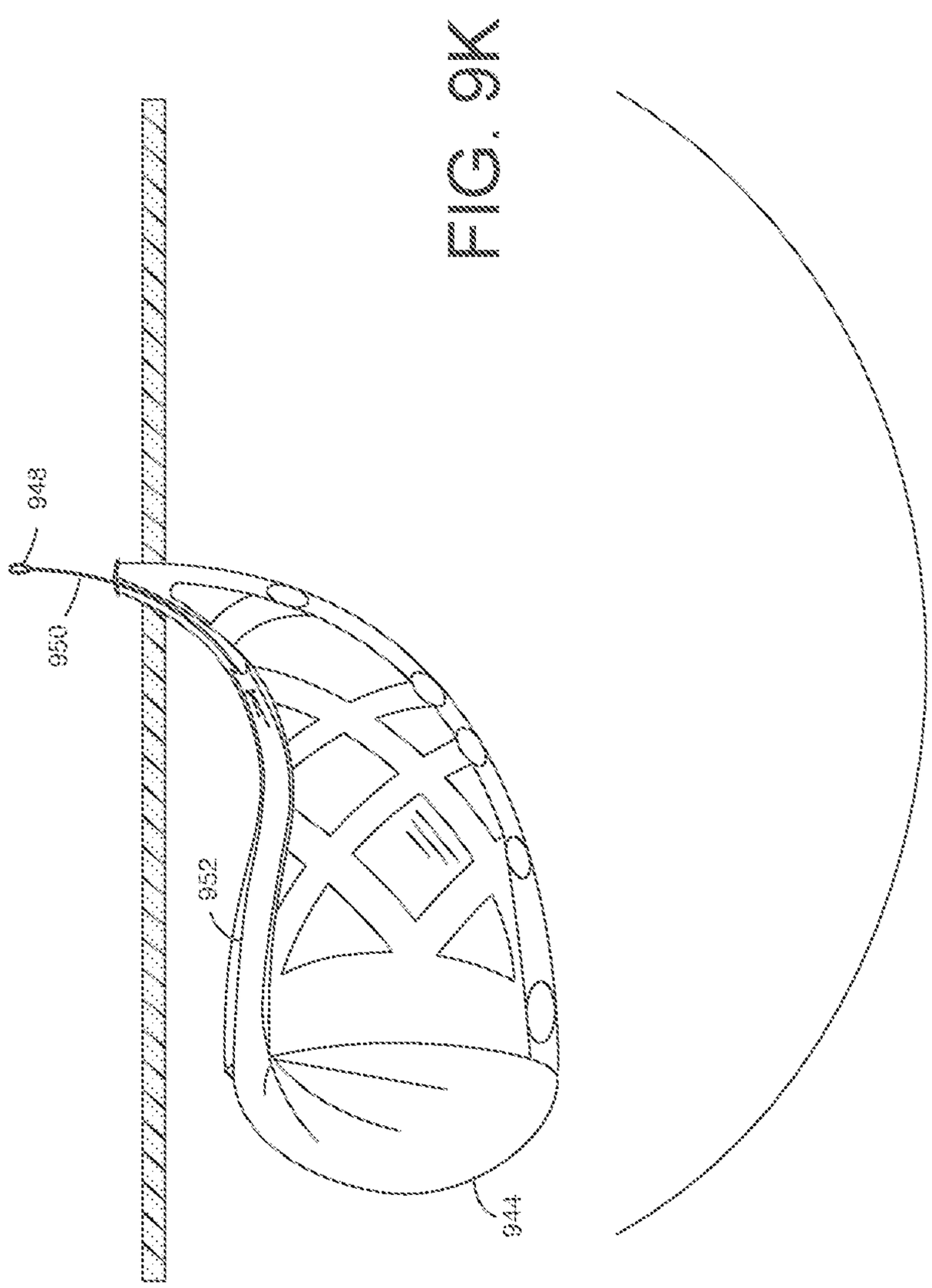


FIG. 9

FIG. 9L

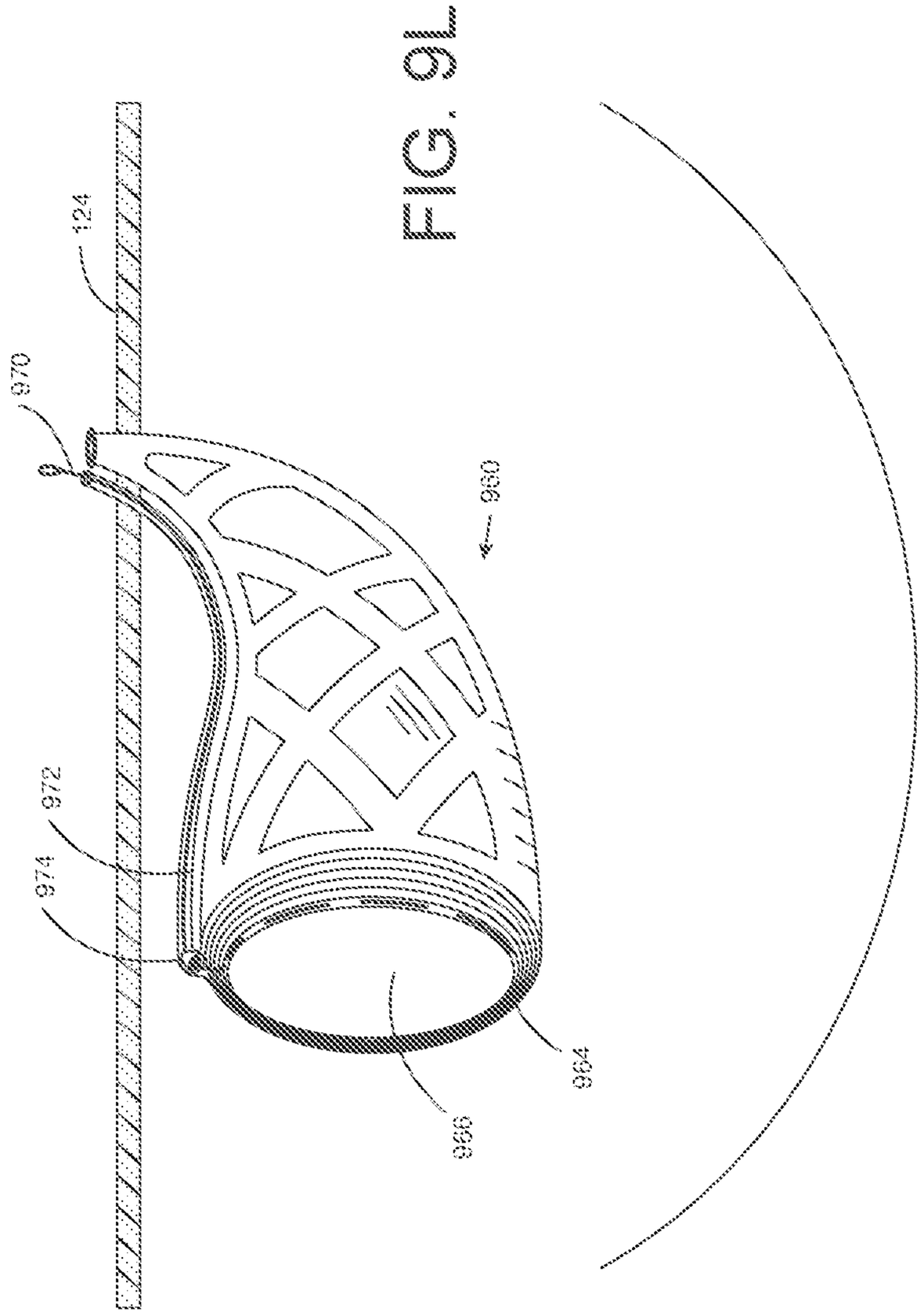
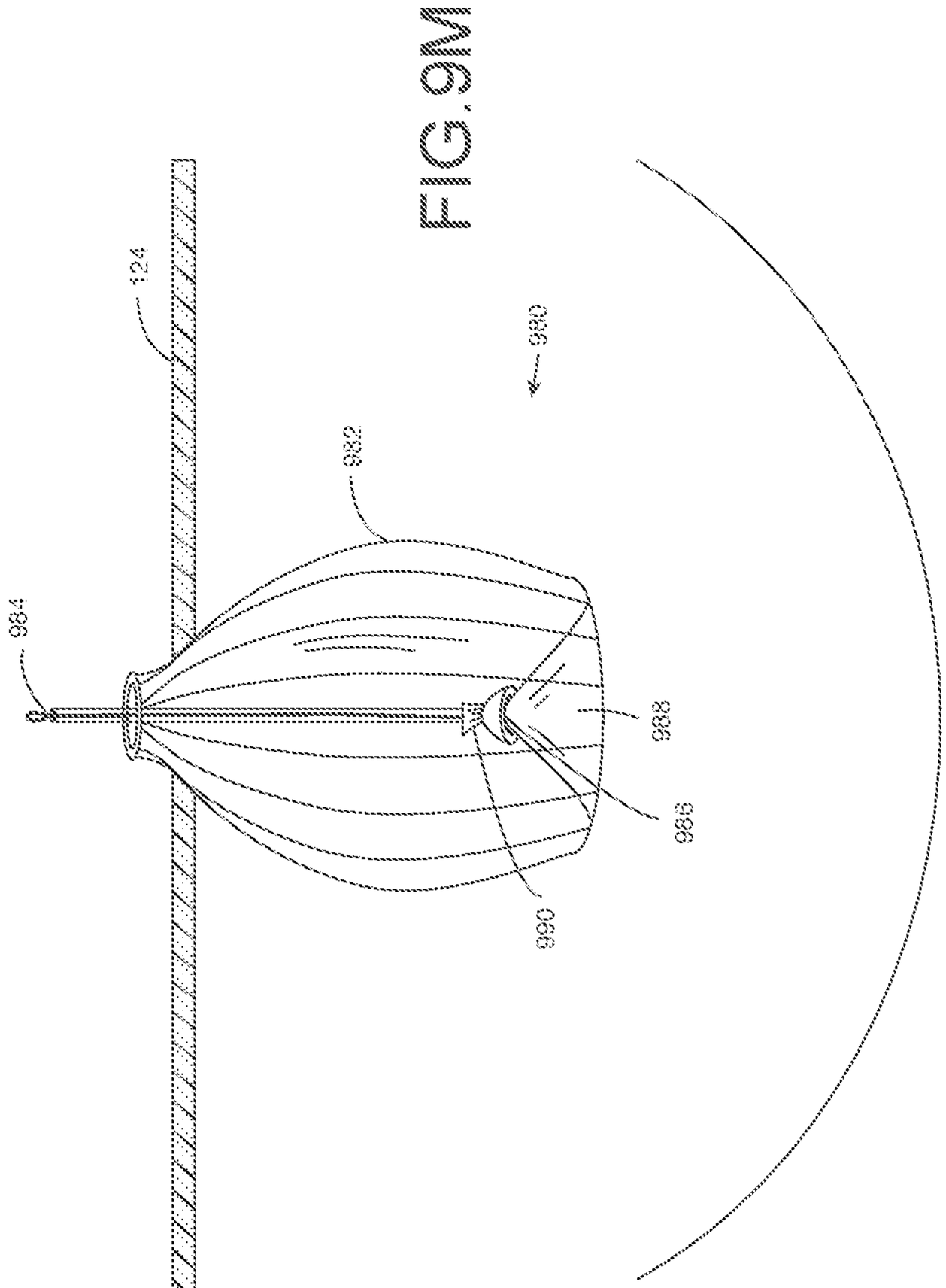


FIG. 9A



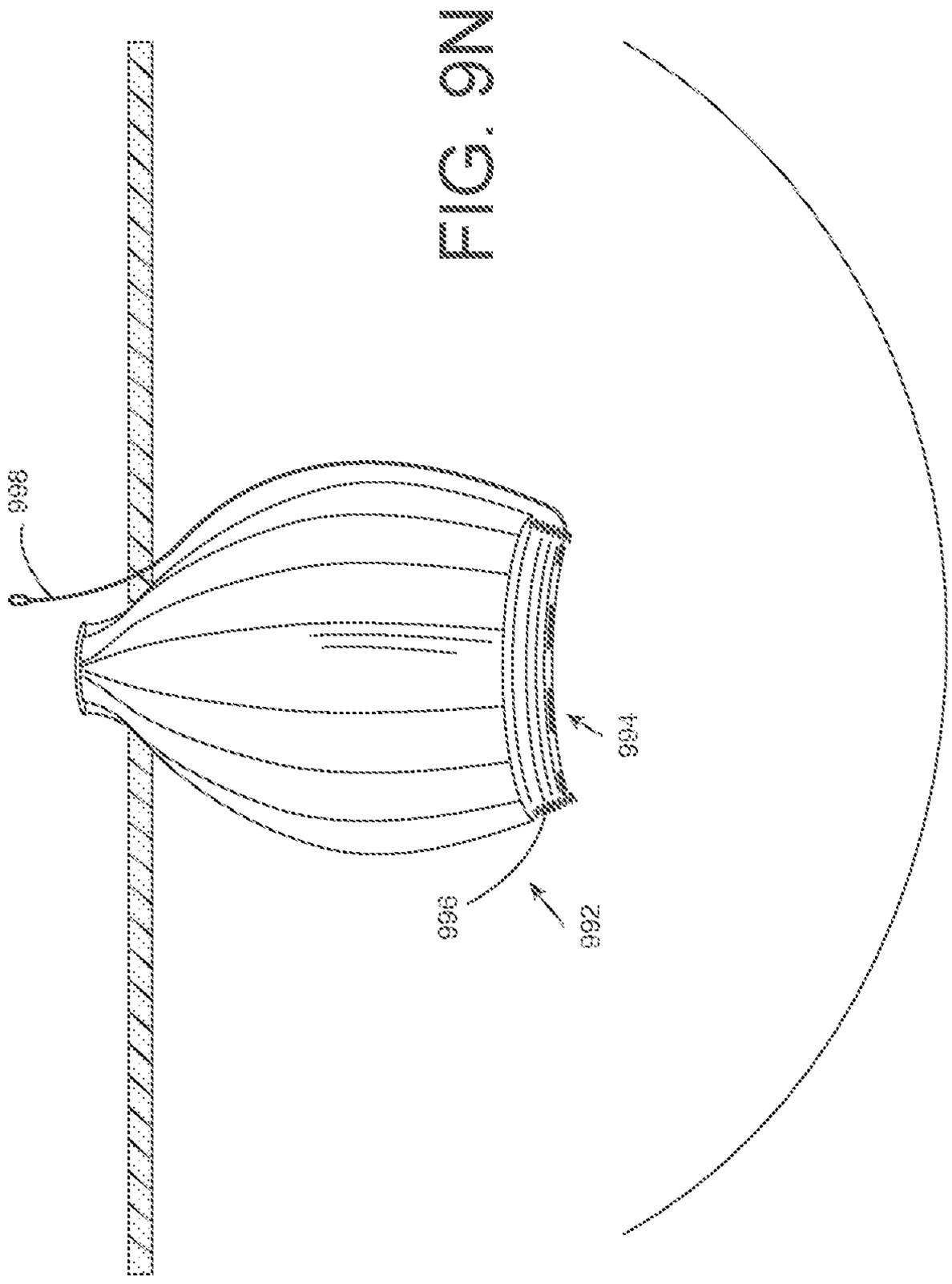
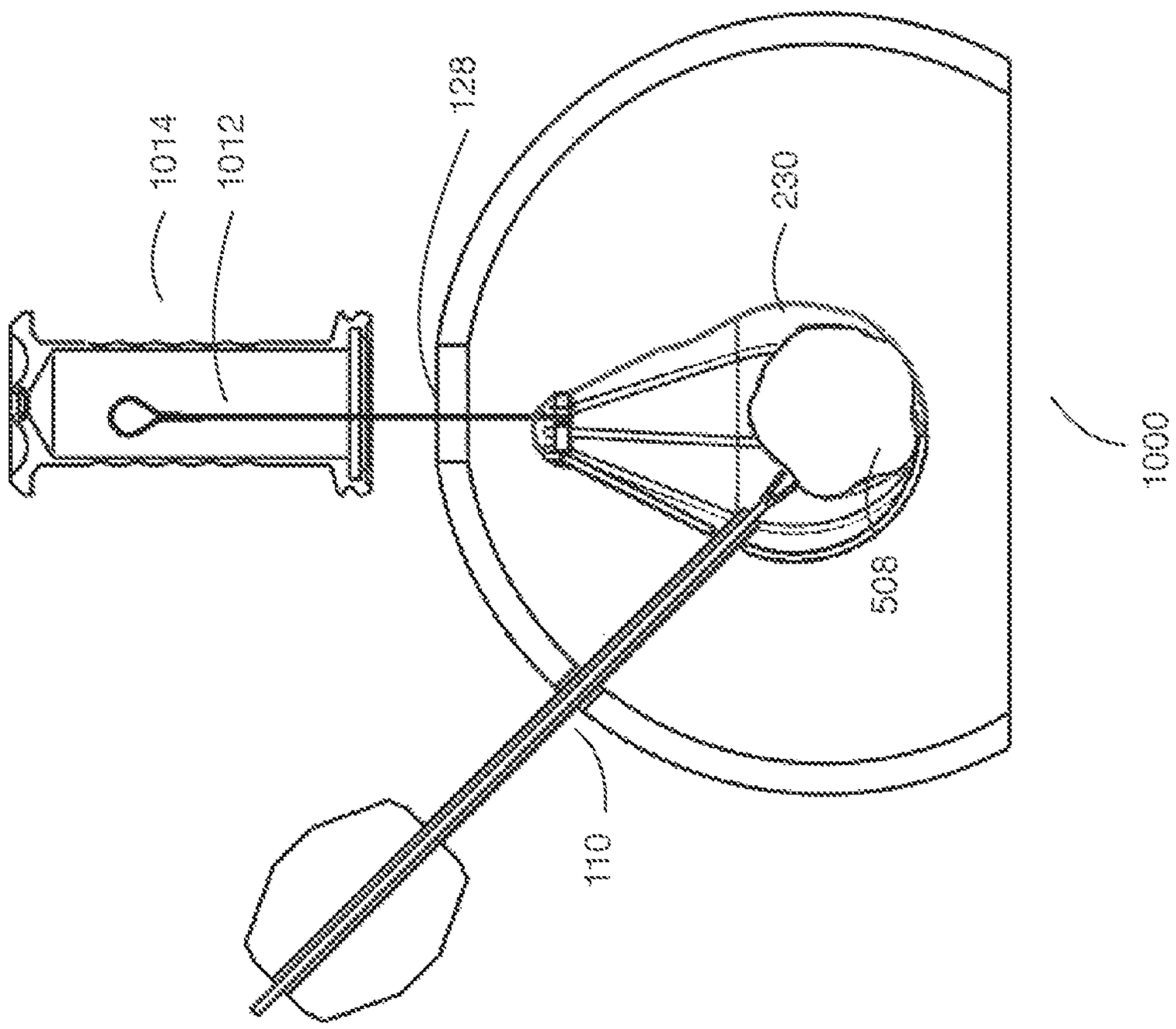


FIG. 9N

FIG. 10A



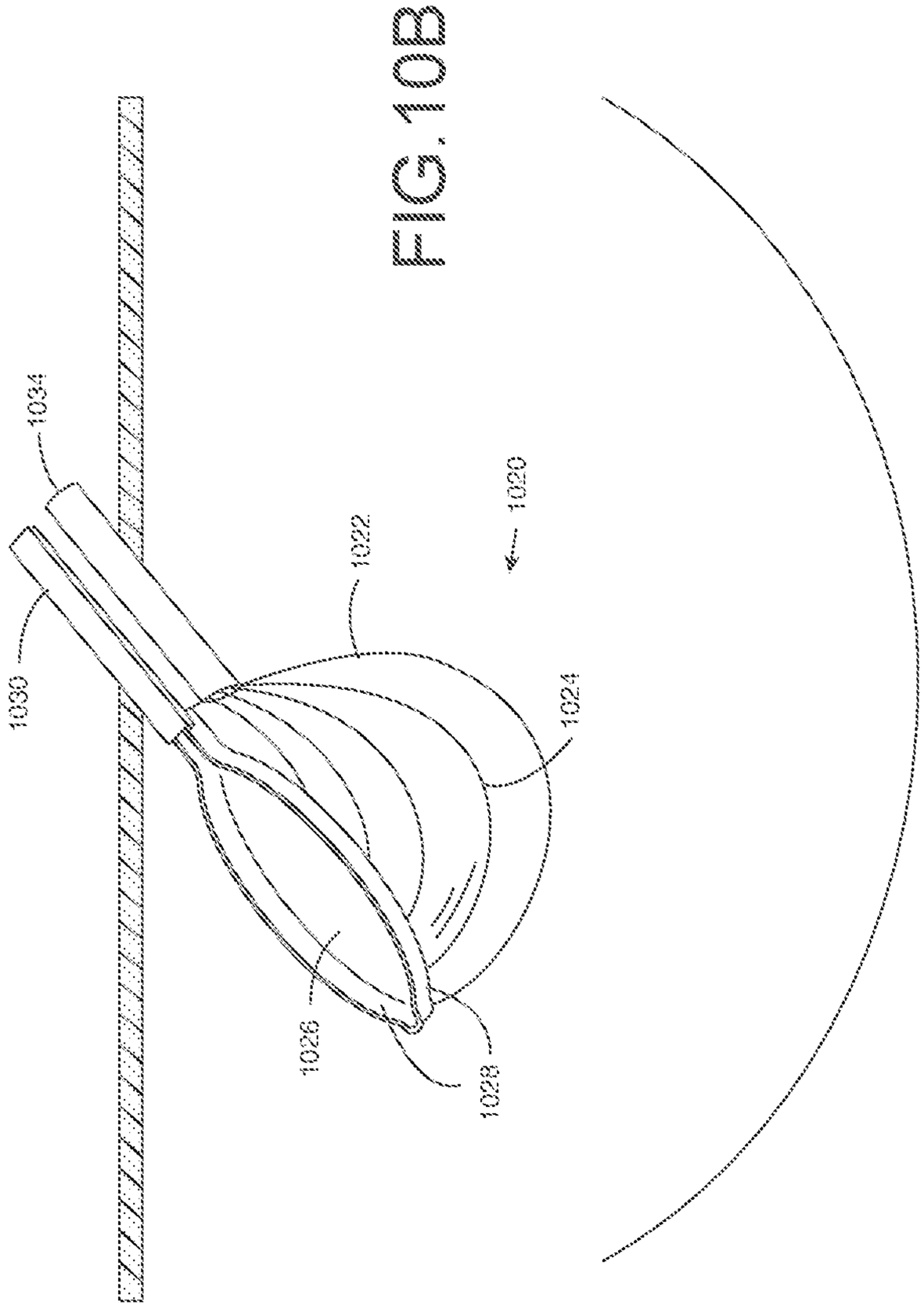


FIG. 10

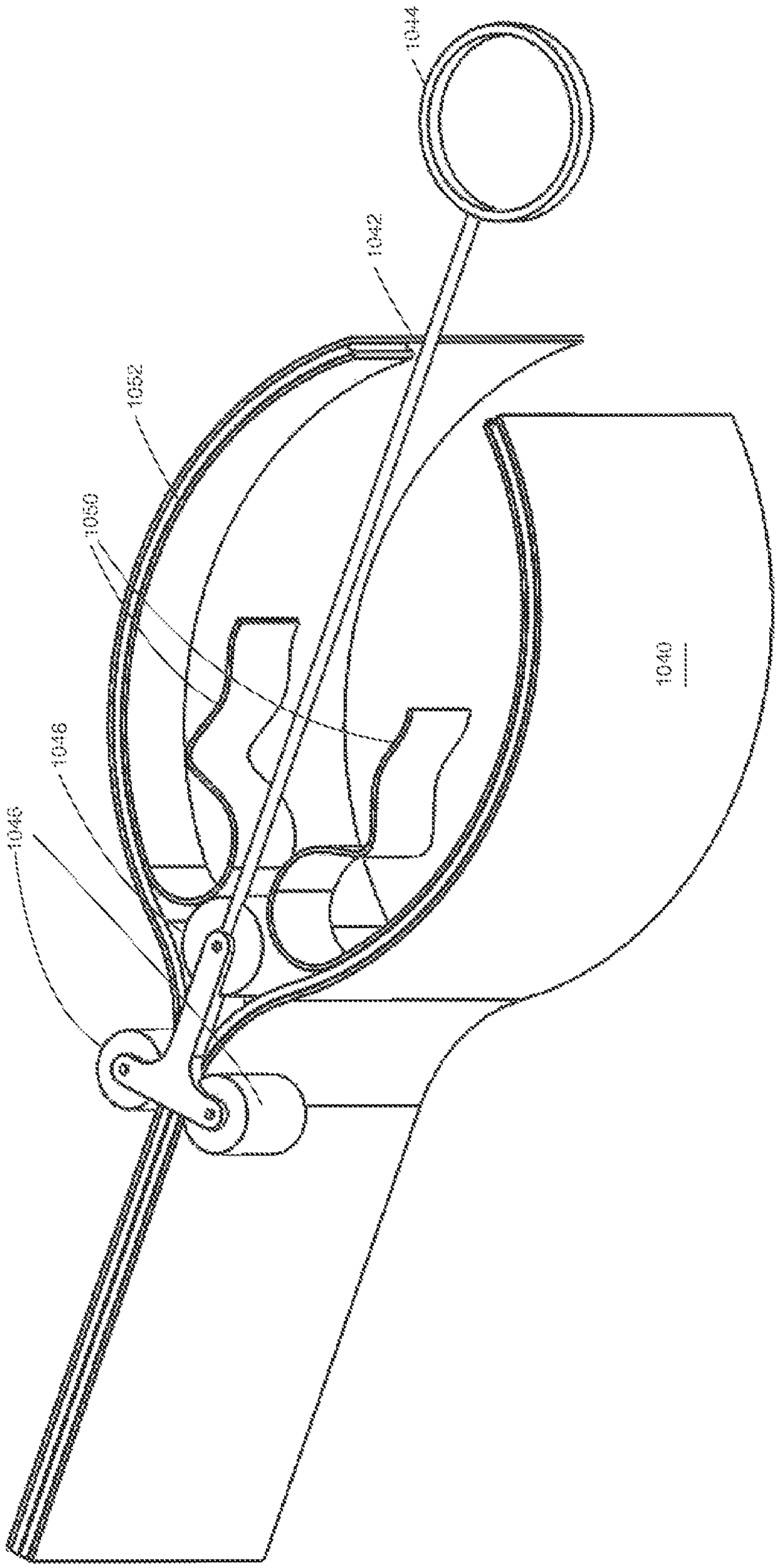


FIG. 10C

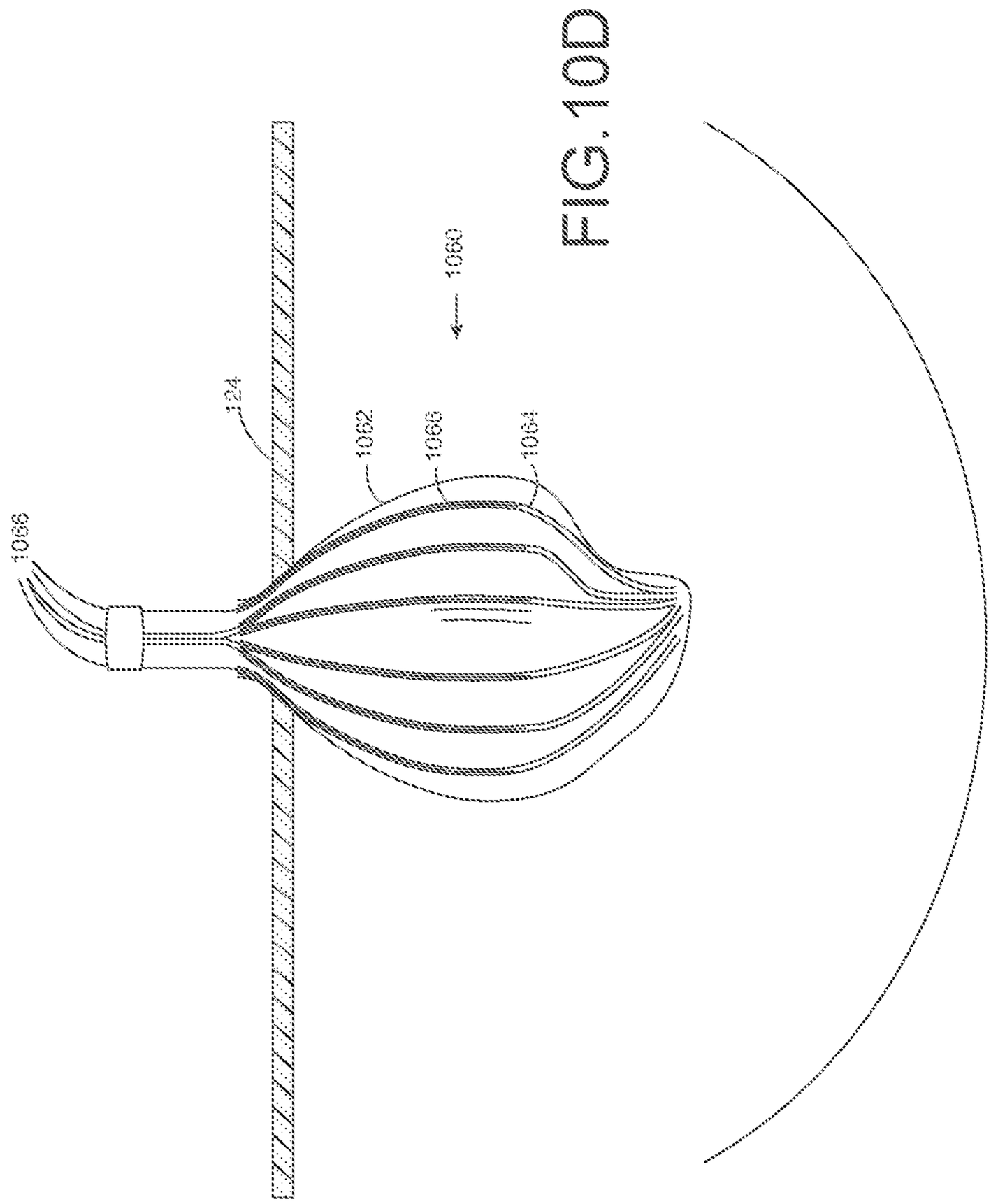


FIG. 10A

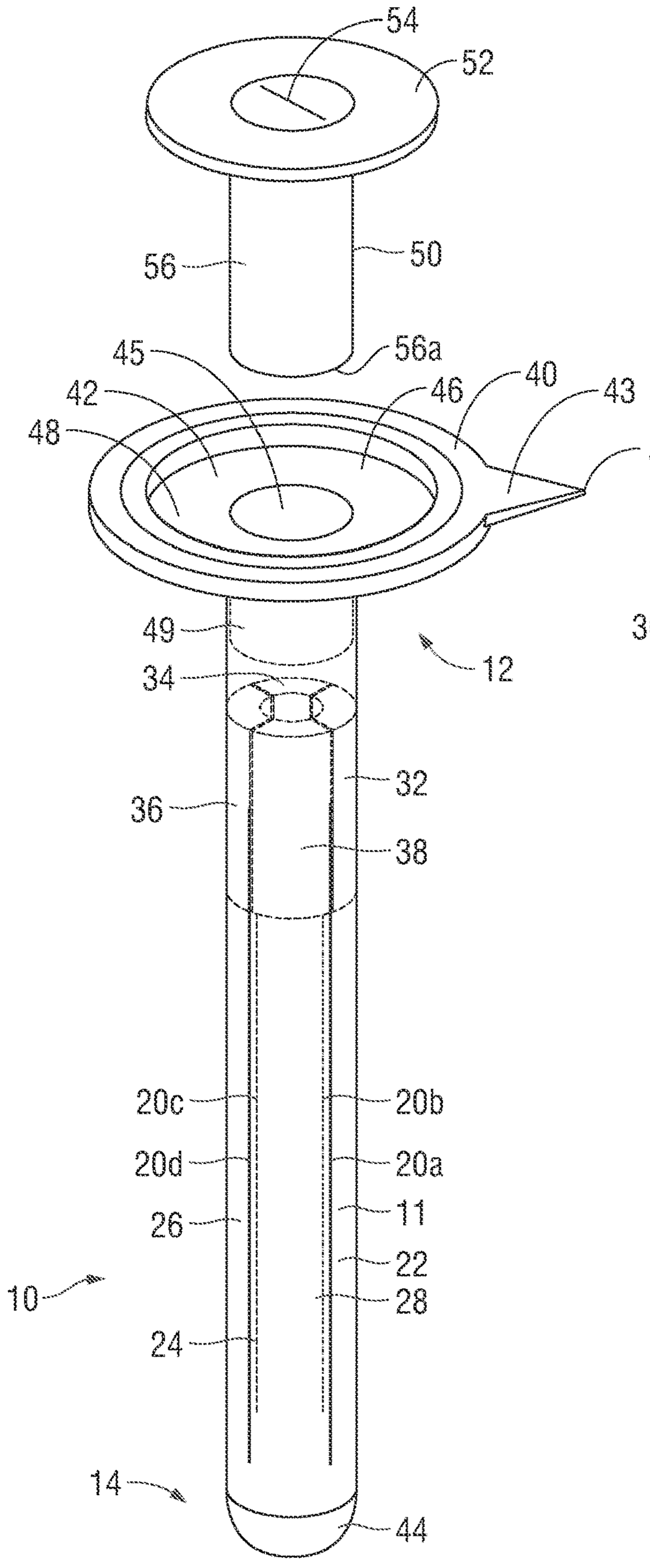


FIG. 11

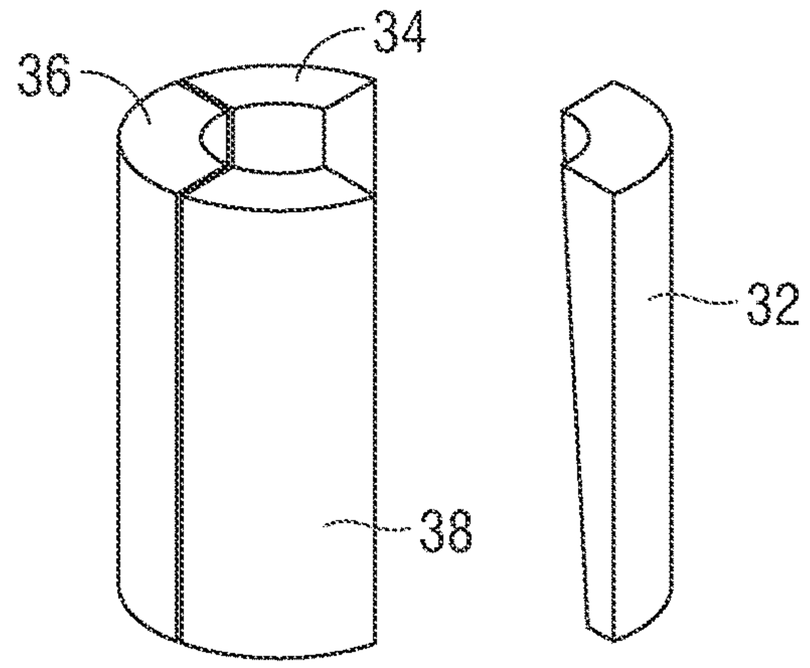


FIG. 11A

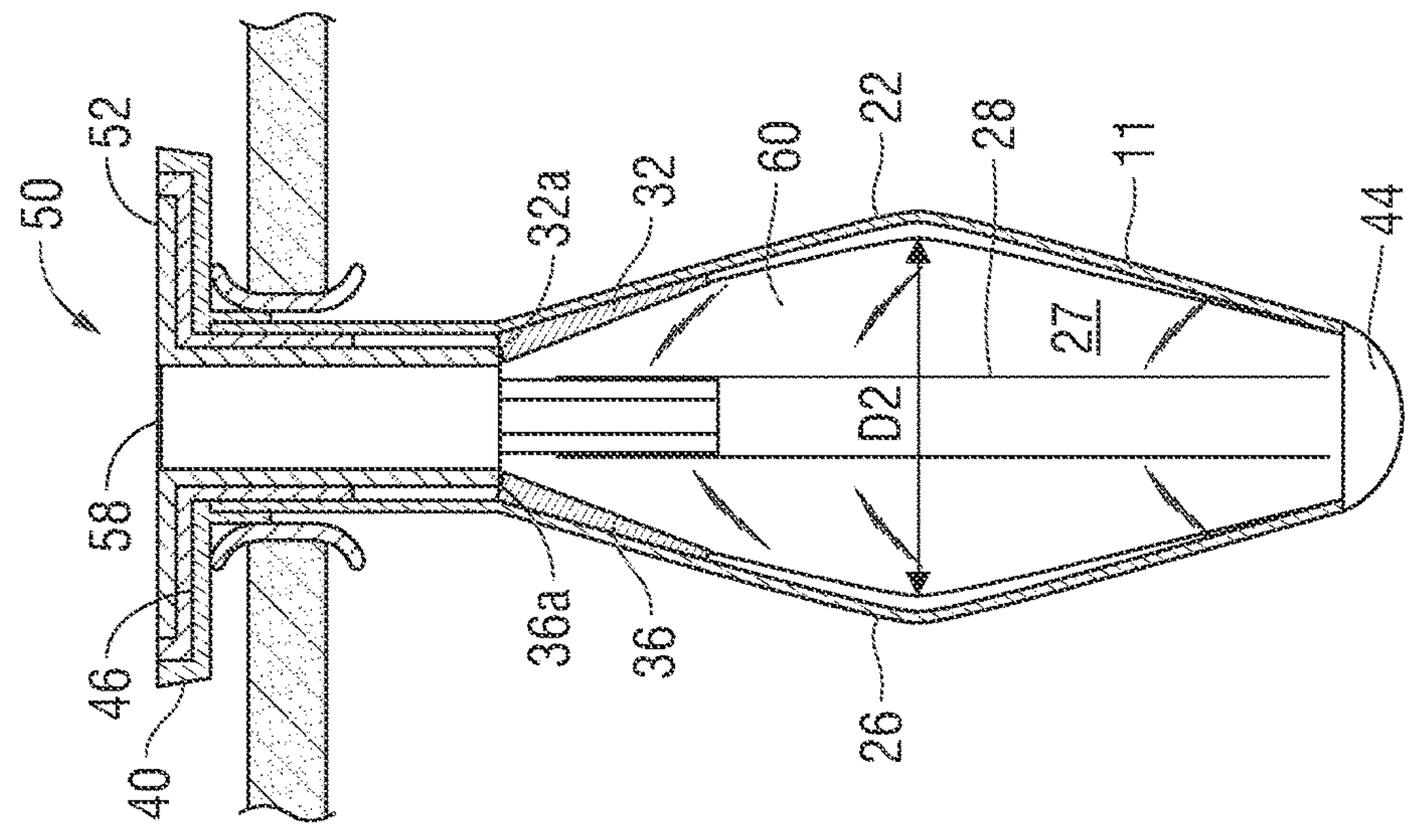


FIG. 12B

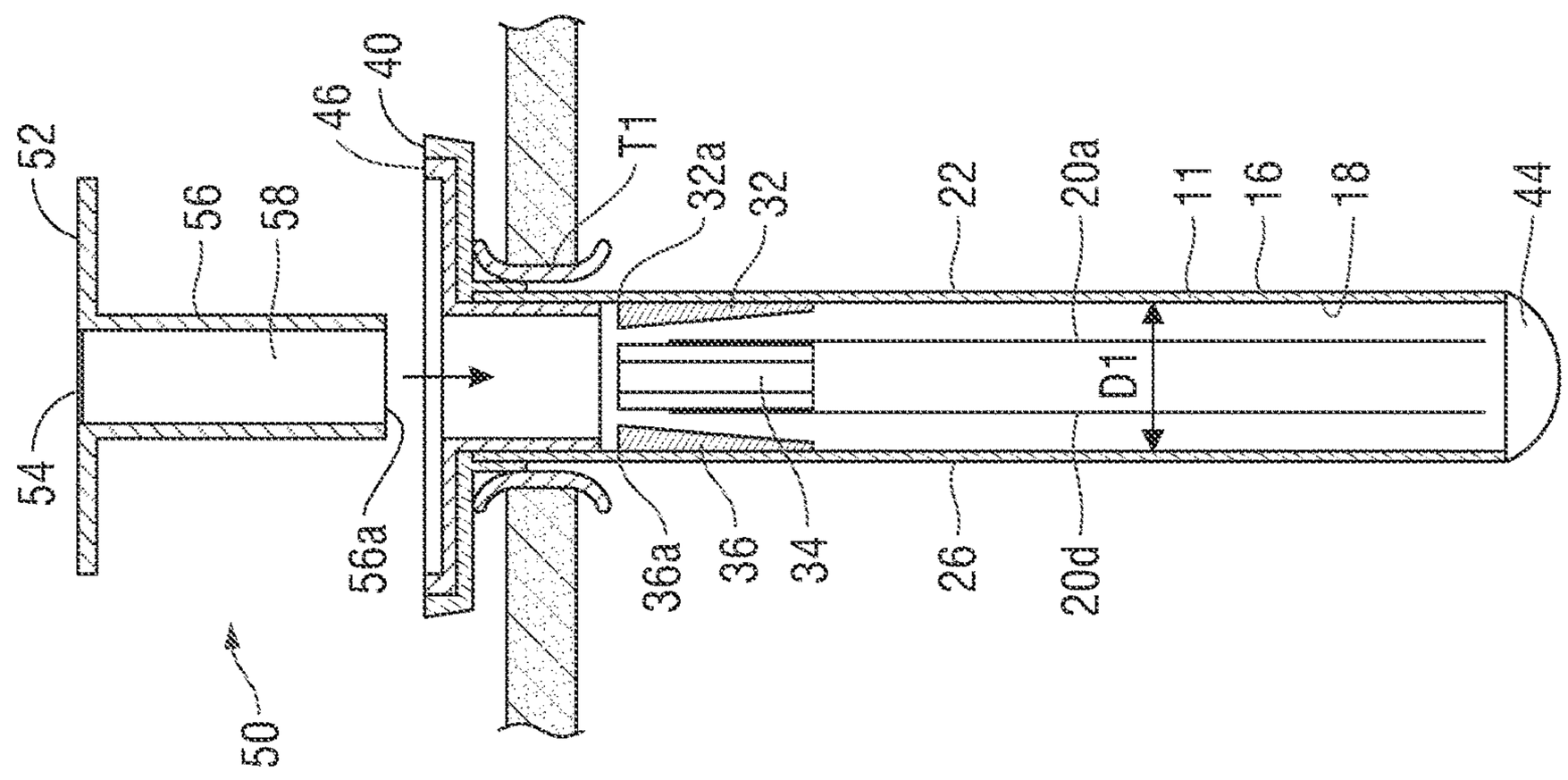


FIG. 12A

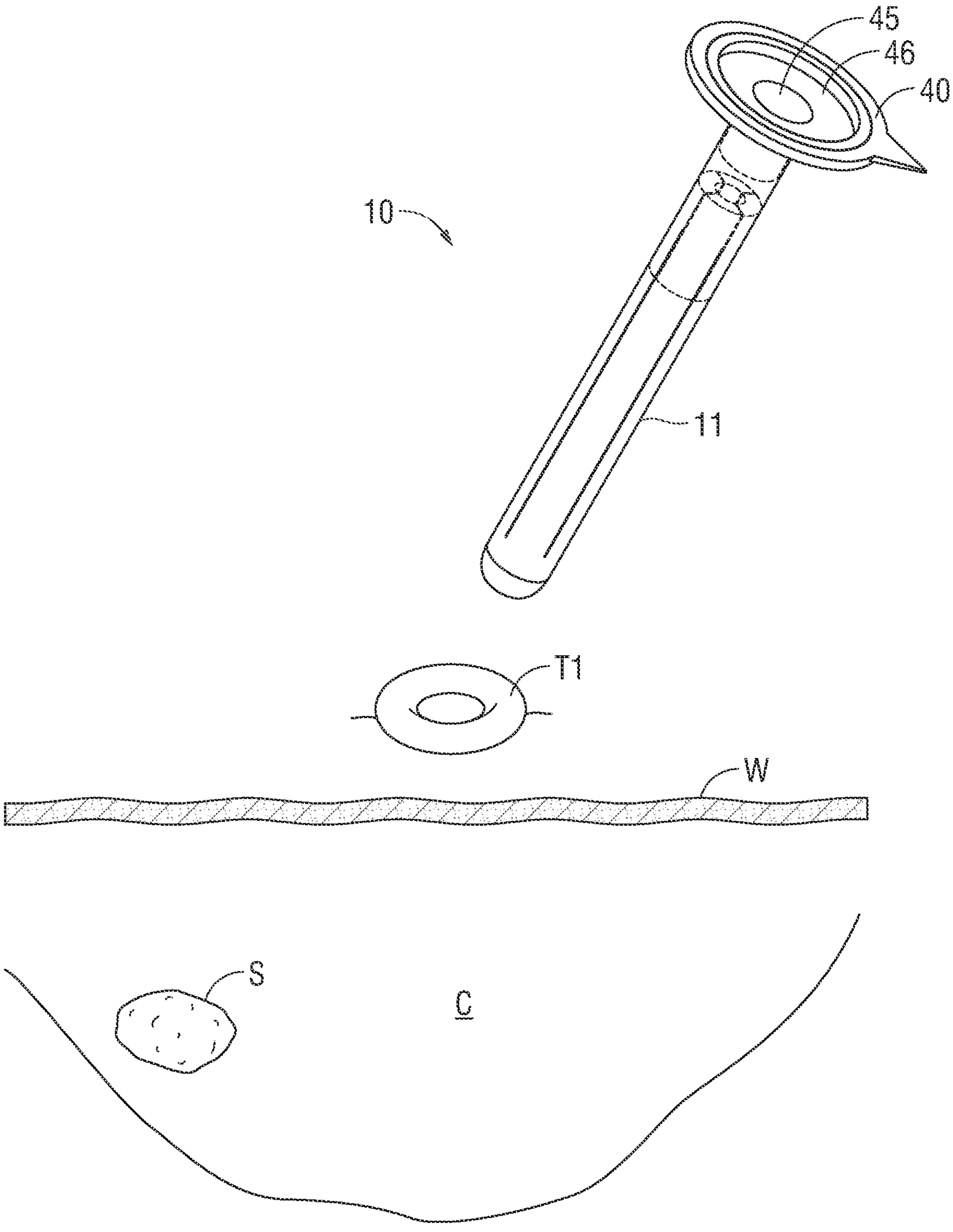


FIG. 13

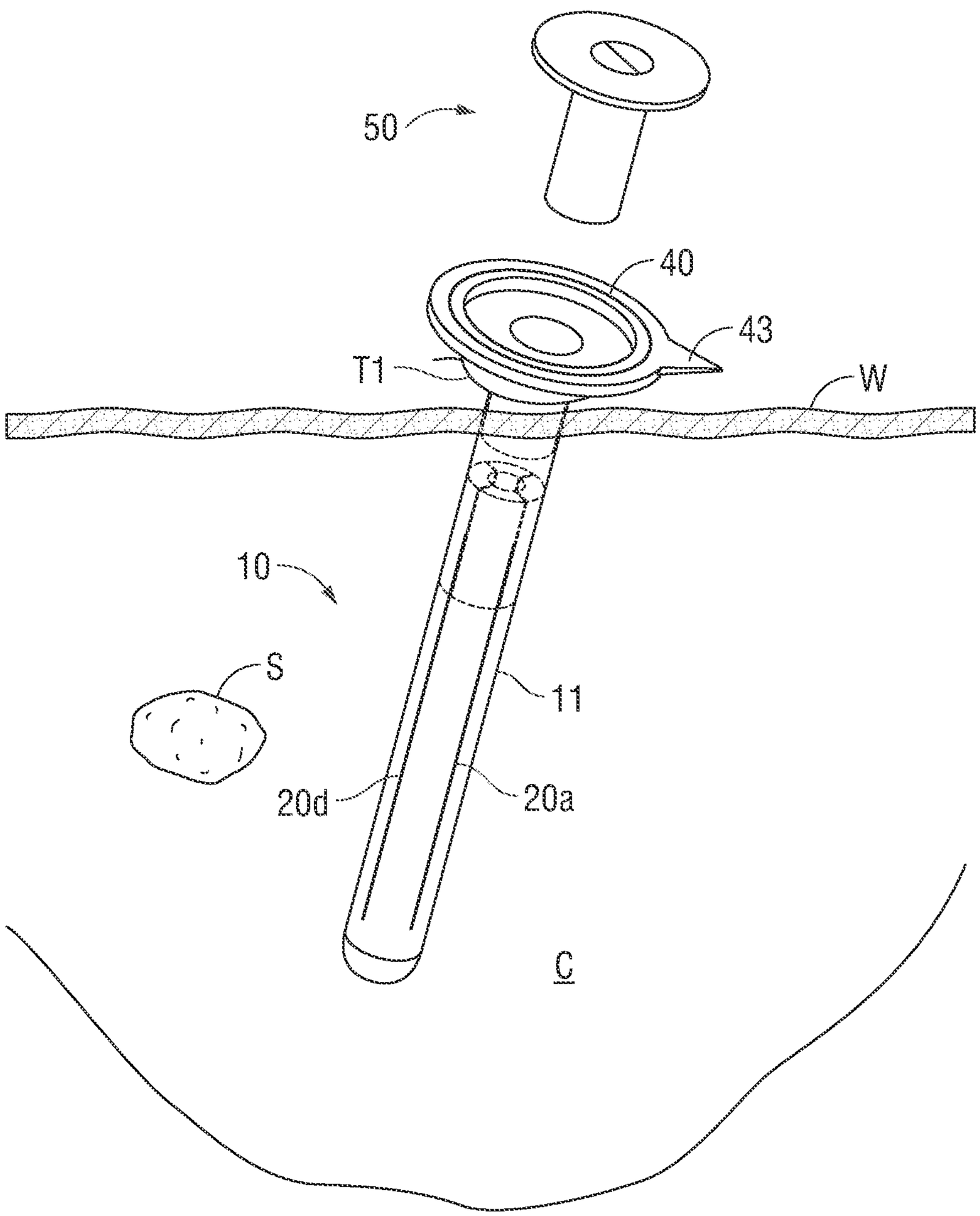


FIG. 14

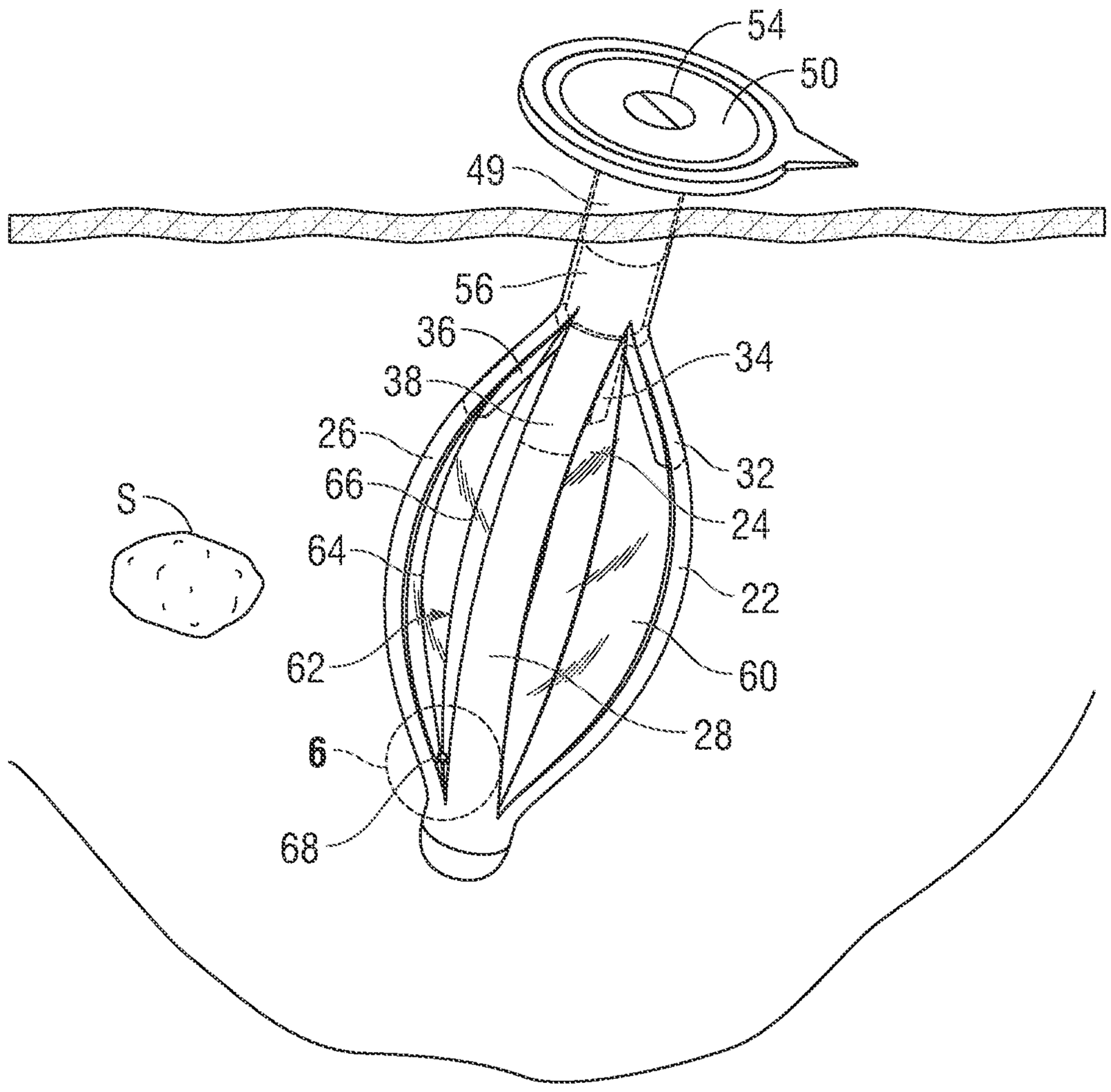


FIG. 15

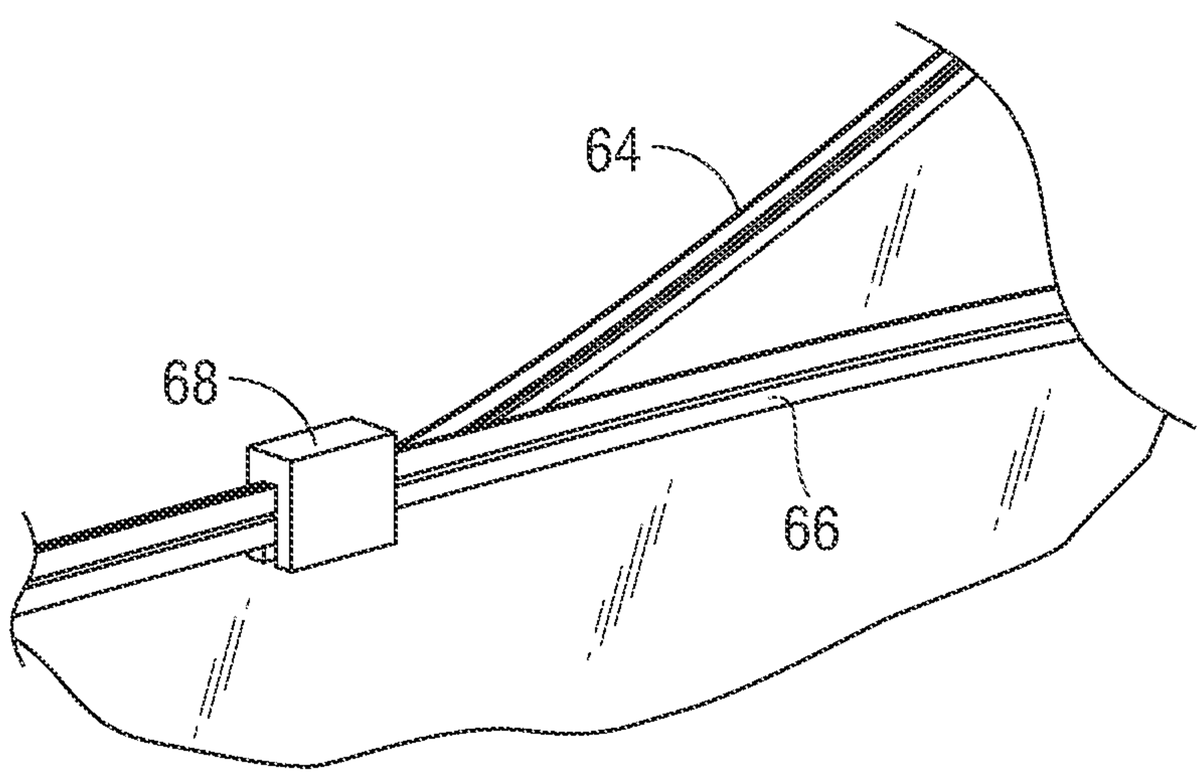


FIG. 16

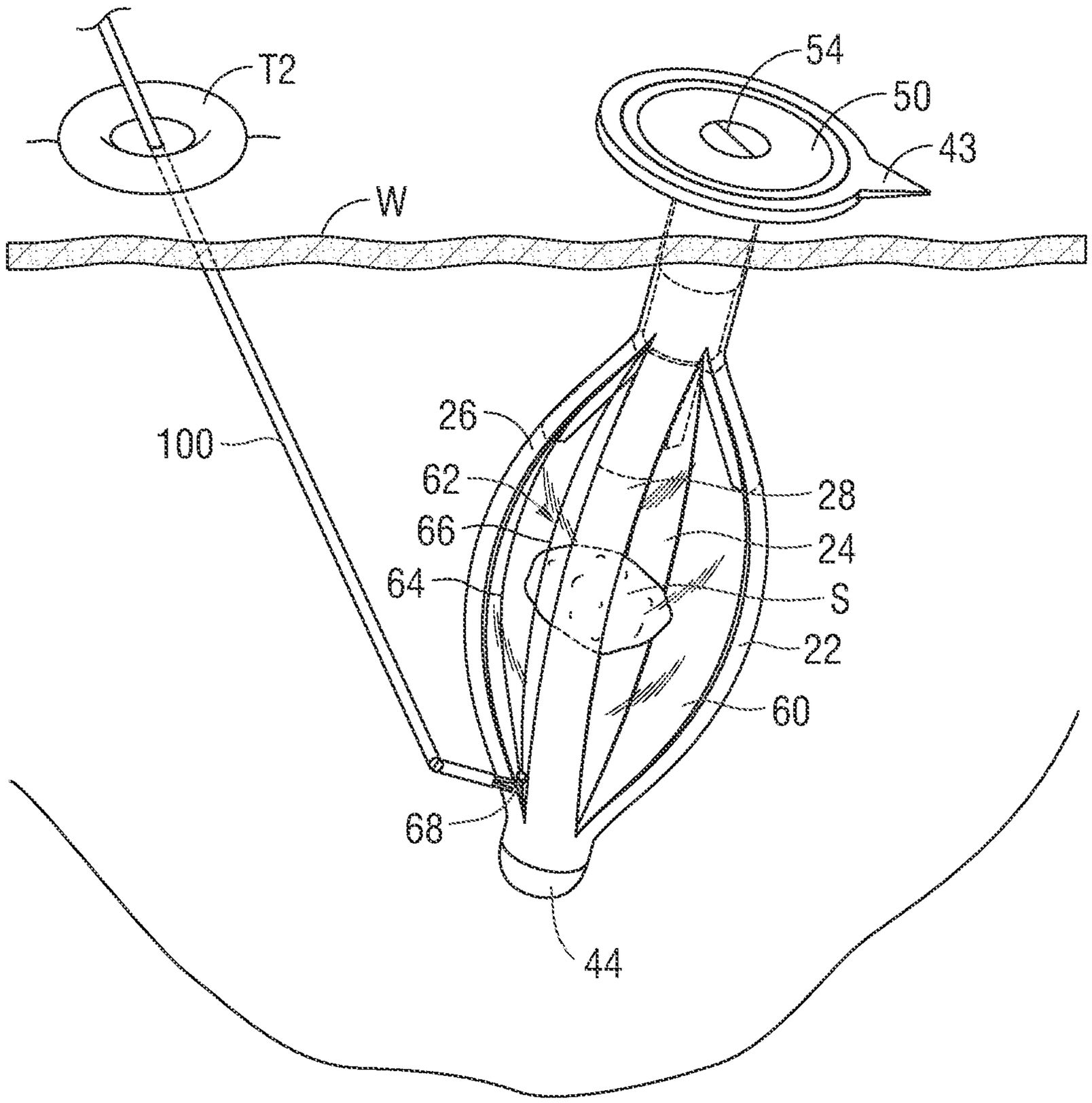


FIG. 17

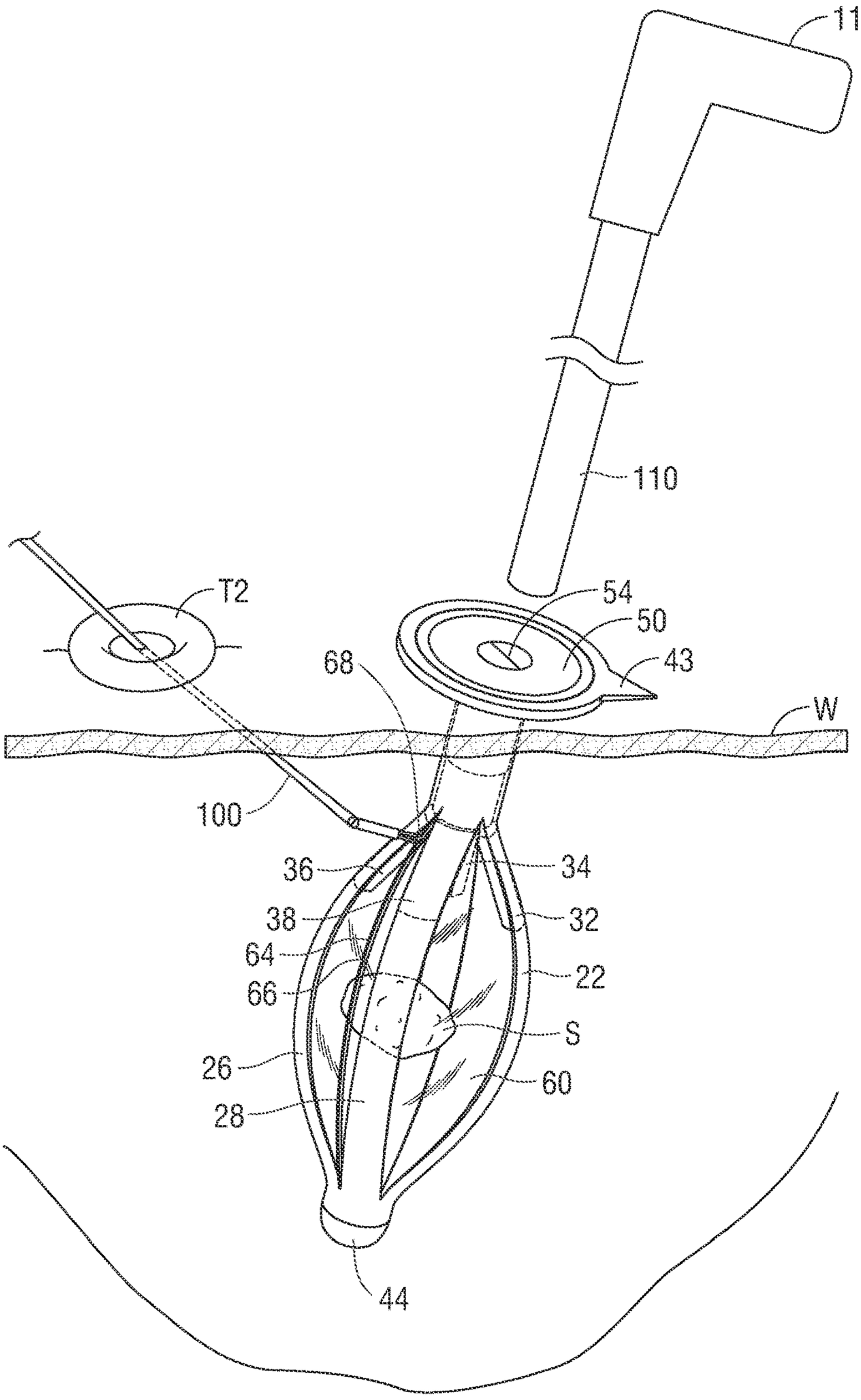


FIG. 18

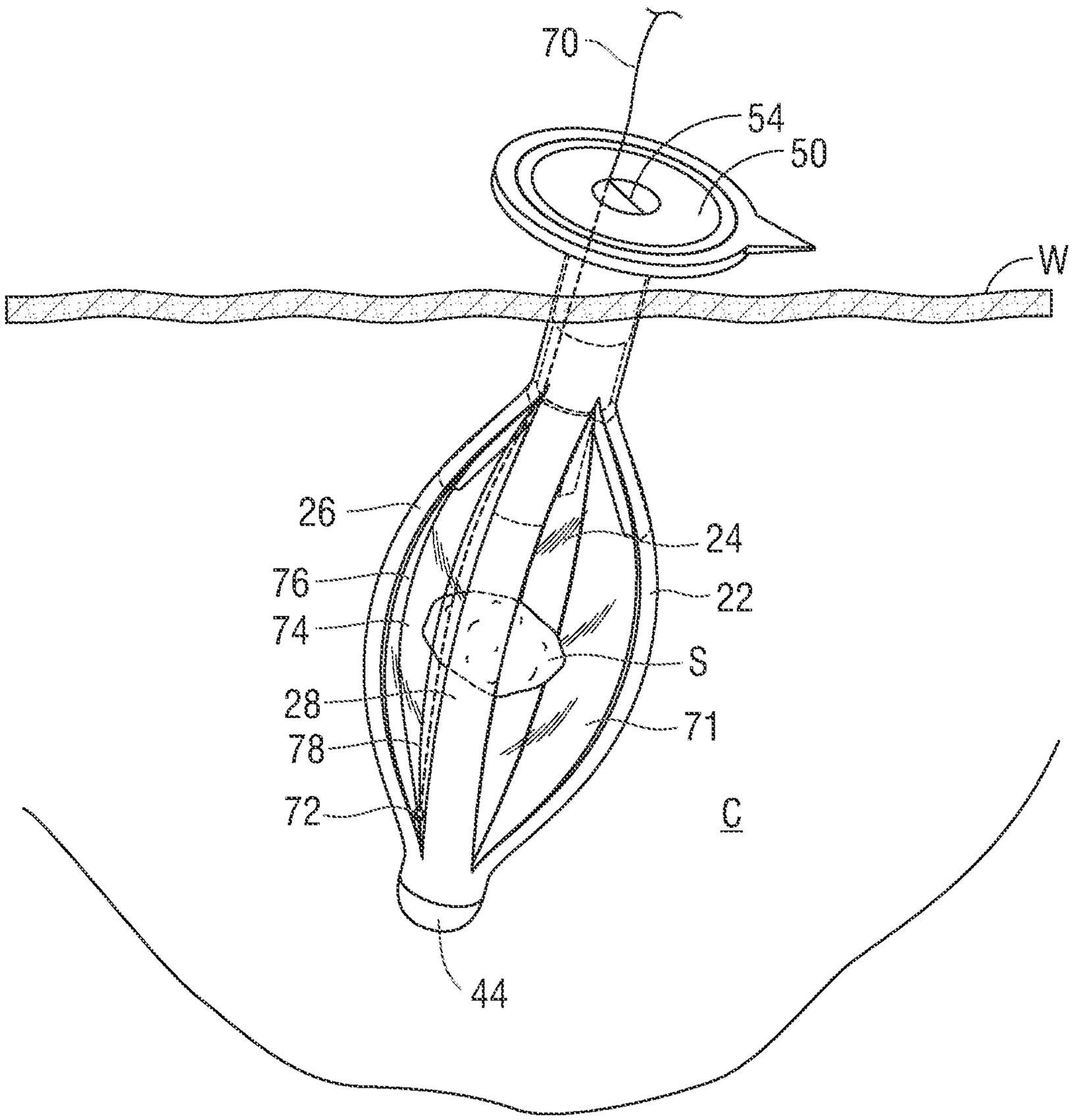


FIG. 19

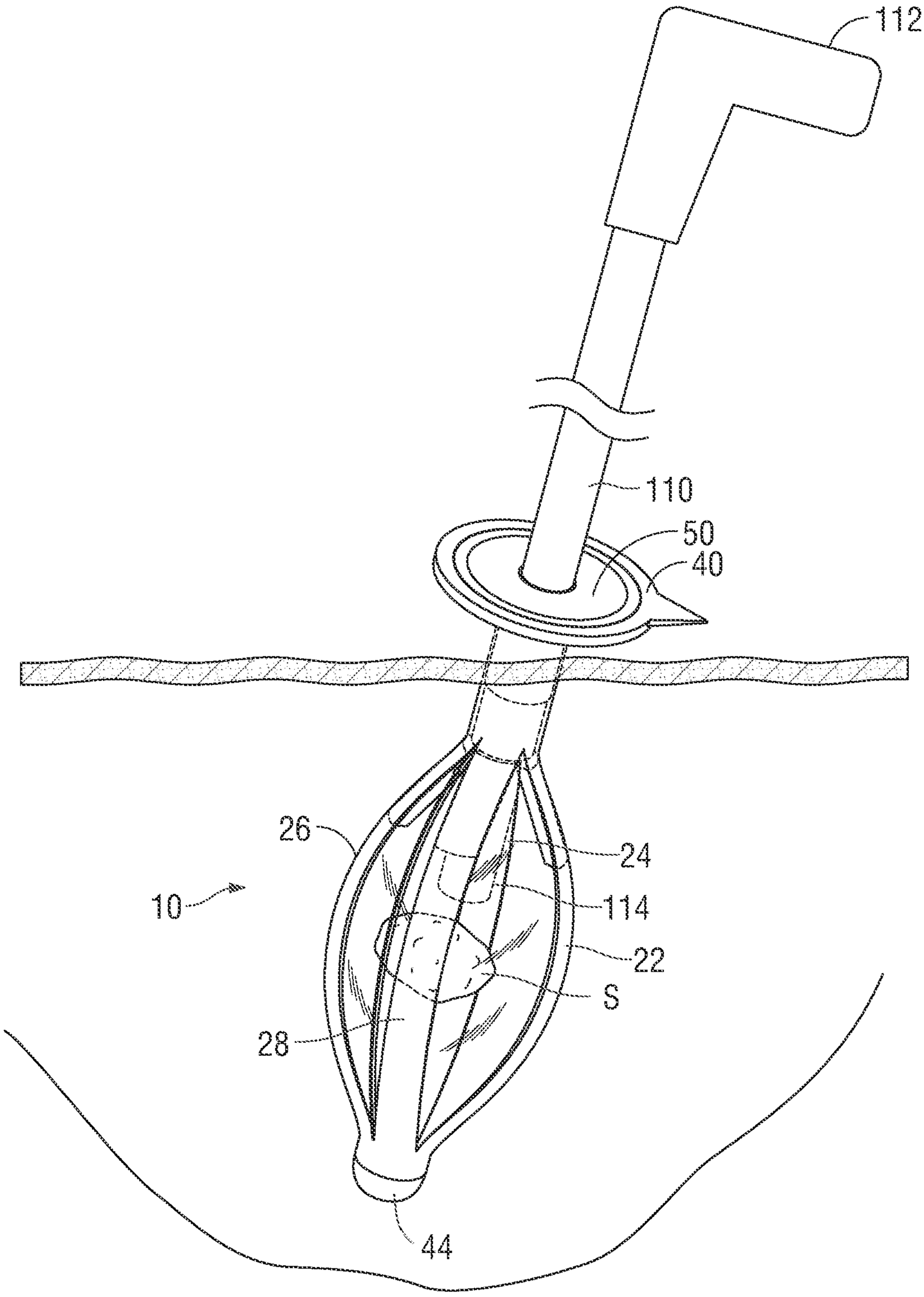


FIG. 20

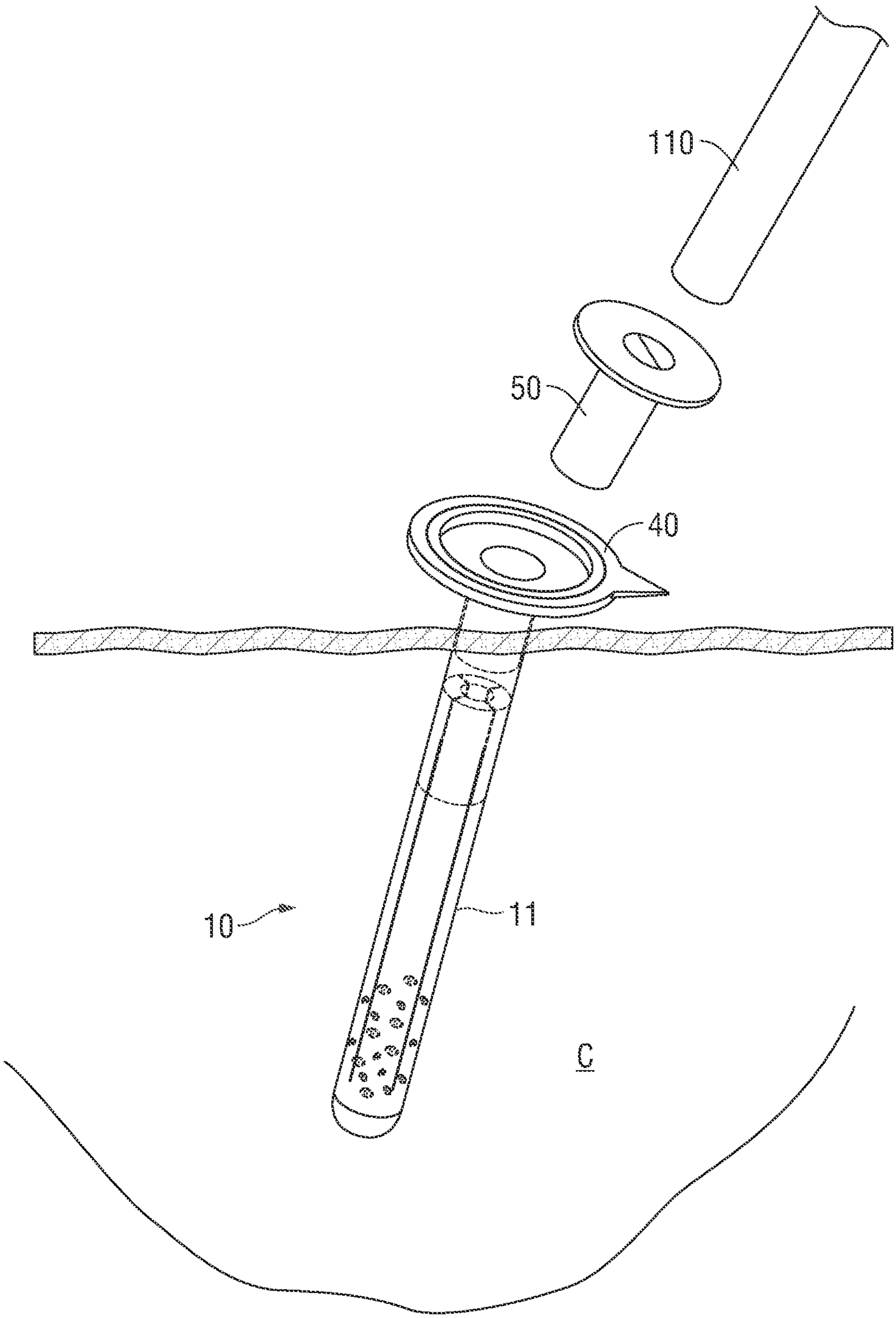


FIG. 21

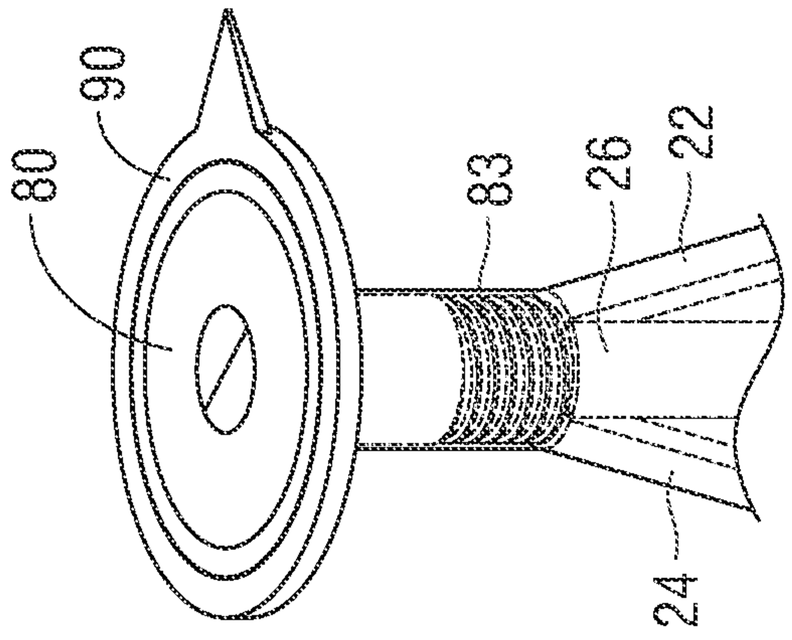


FIG. 22C

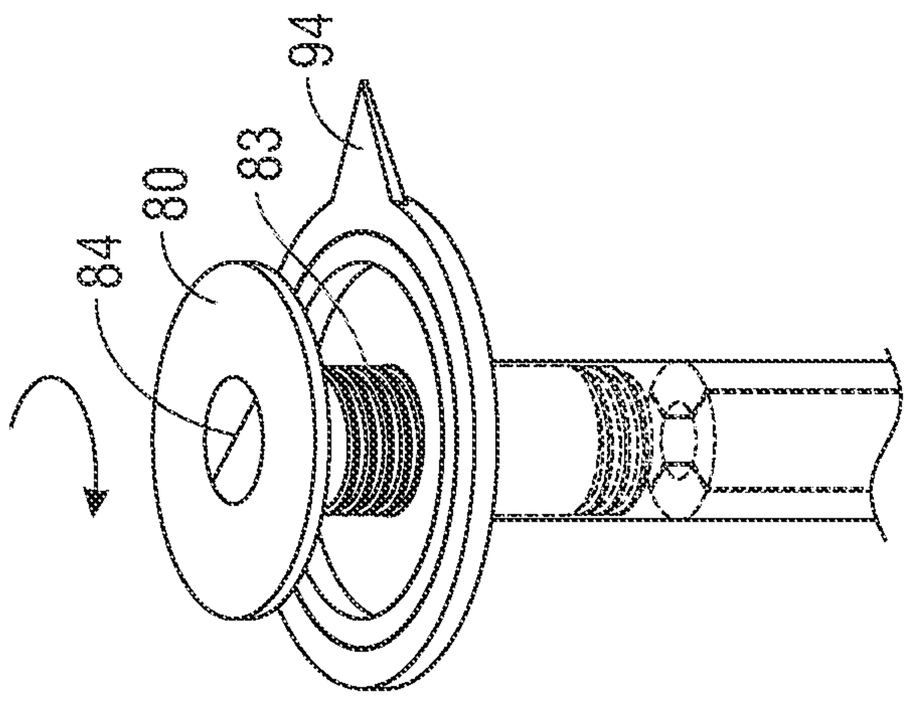


FIG. 22B

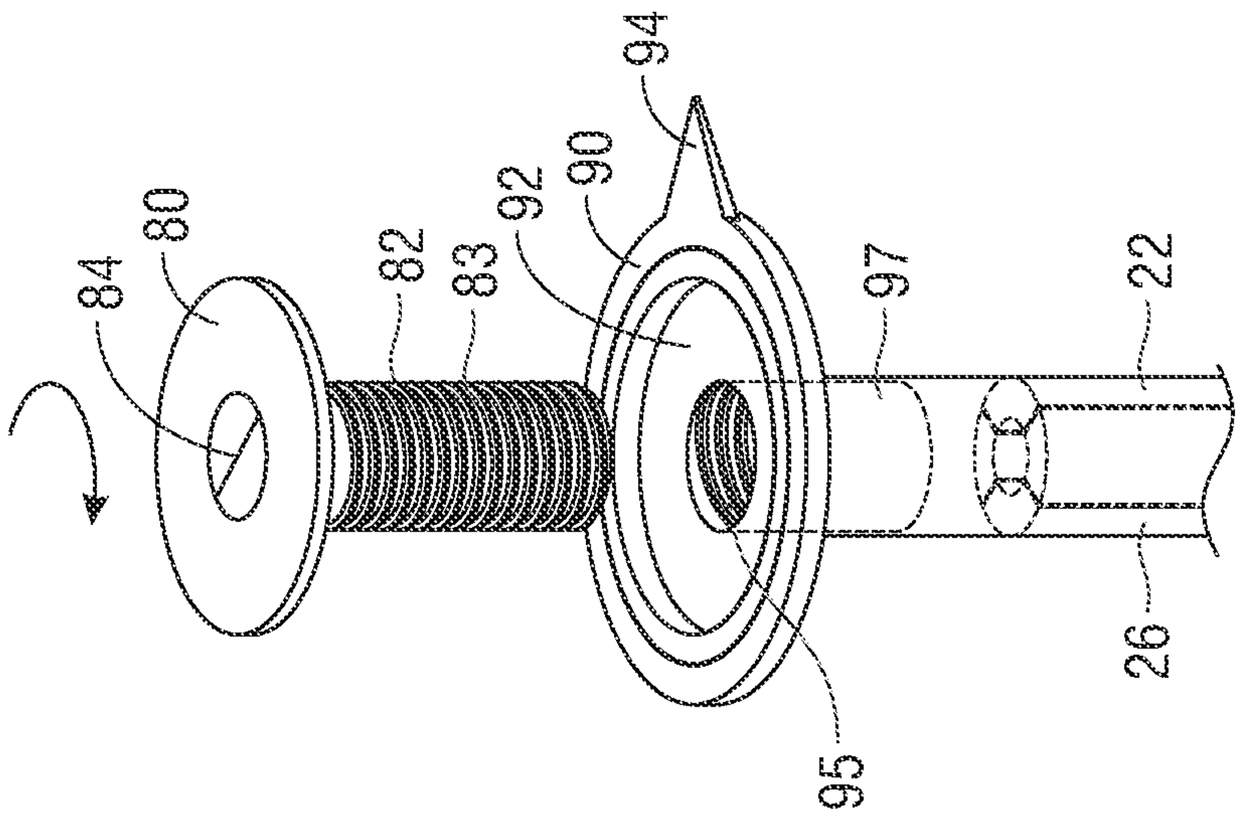


FIG. 22A

FIG. 23C

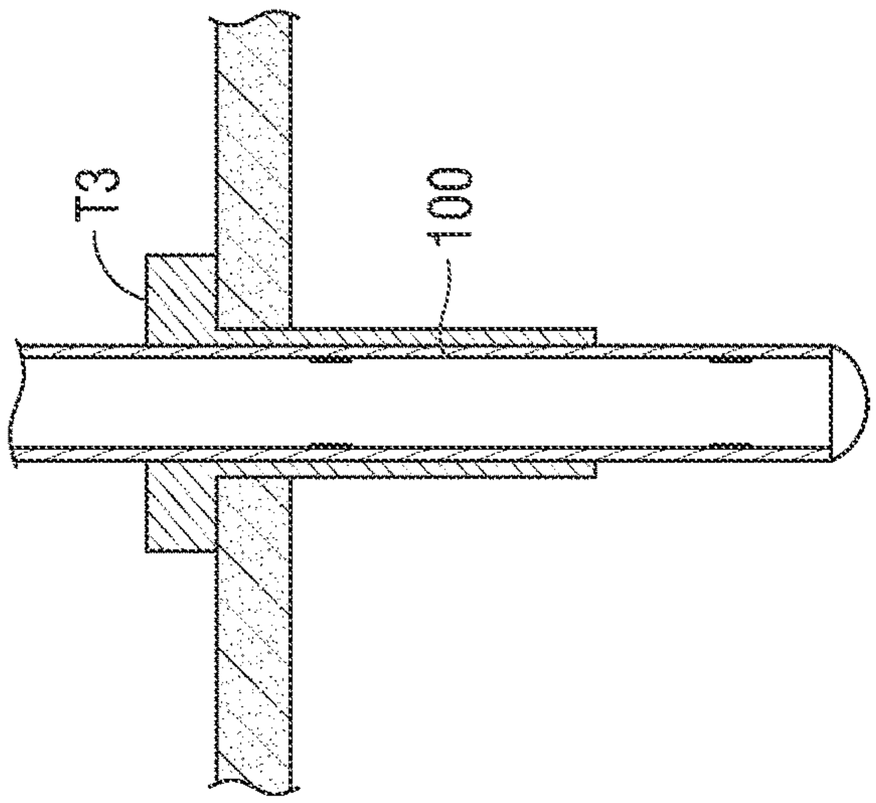


FIG. 23B

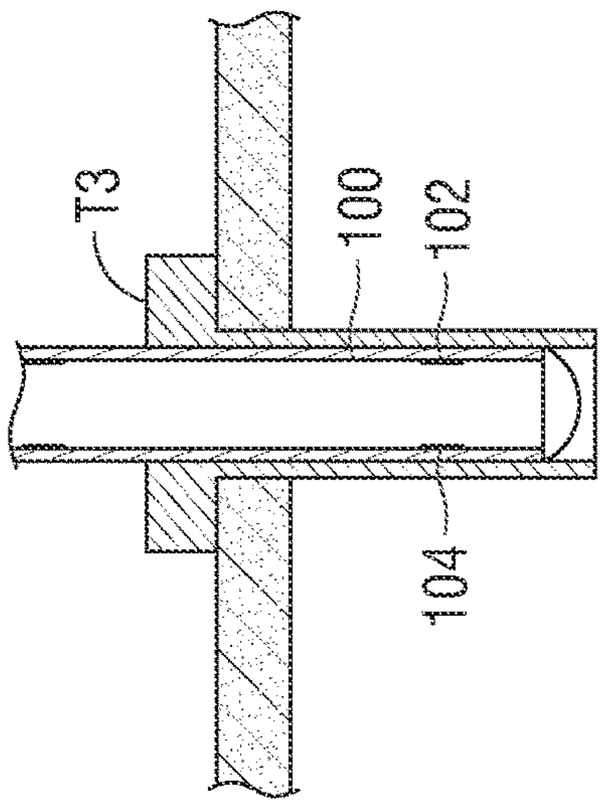


FIG. 23A

LAPAROSCOPIC WORKSPACE DEVICE

RELATED APPLICATIONS

This application is a National Phase of PCT Patent Application No. PCT/IL2017/051015 having International filing date of Sep. 10, 2017, which claims the benefit of priority under 35 USC § 119(e) of U.S. Provisional Patent Application No. 62/393,015 filed on Sep. 10, 2016 The contents of the above applications are all incorporated by reference as if fully set forth herein in their entirety.

TECHNICAL FIELD

This application relates to a device used in reduced invasiveness surgery, for example, but not exclusively, to a laparoscopic device which may be used for specimen removal.

BACKGROUND OF RELATED ART

Every year about 15-20 million laparoscopic procedures are performed worldwide. The advantages of laparoscopy (minimally invasive surgery) over laparotomy (open surgery) are well recognized and include reduced morbidity, less time in the hospital, faster recovery time and reduced costs to the patient and surgery center.

Many of the laparoscopic procedures include the removal of internal organs, such as cholecystectomies, nephrectomies, myomectomies, ovarian cystectomies etc. The removed organs can either be solid or cystic. Currently, there are several ways to remove the mass. One way is by creating an incision in the abdominal wall that allows the removal of the mass. This converts the procedure to a laparotomy or minilaparotomy with the attendant disadvantages of open surgery. Another way is by removing the mass through the cul-de-sac, by performing an incision at the vaginal apex (culdotomy). This disadvantageously requires another incision and also has the disadvantages of increased injury and infection. A third way is by draining the cystic mass and then removing the cyst capsule through one of the laparoscopy ports. The disadvantage of this method is the risk of spillage of the cyst contents. A fourth method of removing the mass is by cutting the large solid mass to smaller particles inside the abdomen and removing the particles through one of the laparoscopy ports or through a culdotomy. Such cutting is achieved by laparoscopic cutting devices which have the disadvantages of scattering tissue in the abdominal cavity and injury to the abdominal organs by the cutting devices.

Another alternative method developed over the years involved the use of a morcellator, a dedicated device that shreds the mass inside the abdomen and allows the removal of the shredded particles through one of the laparoscopy ports. Since 1993, several types of electromechanical and manual morcellators were developed, either disposable or for multiple use. The morcellators allowed fast removal of large abdominal solid masses through a laparoscopy port by reducing the mass size so it could fit through the port. Their use offered patients the benefits of laparoscopic surgery even when large masses had to be removed from the abdominal cavity, such as procedures that involved myomectomy, hysterectomy, removal of large solid adnexal masses or nephrectomy.

For power morcellation, several specimen bags are currently being used. The bag is introduced though a laparoscopy port, the specimen is placed inside the bag, a large laparoscopy port is removed and the free edges of the bag are brought through the incision. Then the port is placed into the bag opening and insufflation is placed through this port. The scope can be placed in two ways: 1) through a port located outside the bag; or 2) through a new port that is placed from the outside into the insufflated bag and is secured by a balloon tip trocar.

U.S. Pat. No. 521,551 describes "Laparoscopy organ retrieval apparatus and procedures are presented for minimum invasion surgery inclusive of laparoscopic nephrectomy, cholecystectomy and other organ dissection, morsellation removal from the abdomen through a keyhole incision. The apparatus and procedures permit the safe and total removal of an organ from a body cavity in a morsellated condition through the combination utilization of an entrapment envelope sheath. The entrapment envelope having an apparatus for opening and closing, the apparatus controlled from an exterior position of the body cavity wherein the entrapment envelope after entry of the sheath is extruded from the sheath which has been inserted through a laparoscopic port in place in a keyhole surgical opening. The entrapment envelope is constructed of flexible, relatively low bulk fluid impermeable materials having sufficient strength to contain morsellator entry, organ fragmentation and removal."

US patent application publication 2004/0097792 describes "A method of providing access to tissue for a surgical instrument through a body wall is provided. The method includes providing an expandable retractor having a flexible sheath, the retractor being in a collapsed state; introducing the retractor into the body and placing the retractor adjacent the tissue; expanding the retractor; deploying the flexible sheath by engaging the flexible sheath with a tool and driving the flexible sheath through the body wall with the tool; and inserting the surgical instrument from outside the body through the flexible sheath to provide access to the tissue by the surgical instrument."

US patent application publication US20150297254 describes "A morcellator shield and bag assembly including a shield having a cavity and a bag coupled to the shield. The bag is moveable between a contracted position, in which at least a portion of the bag is positioned within the cavity, and an expanded position. The bag has an opening that is in fluid communication with the cavity when the bag is in the expanded position. A method for using the assembly along with a morcellator to remove tissue from a body cavity. The method includes inserting at least a portion of the assembly into a body cavity, moving the bag to the expanded position, placing tissue in the bag, pulling the bag through an opening in a patient, inserting the morcellator into the assembly, and morcellating the tissue with the morcellator. The assembly is designed to contain the tissue being morcellated and prevent the morcellator from contacting the bag."

SUMMARY OF THE INVENTION

Some exemplary embodiments of the invention are now noted as the following examples. It is noted that features from one example may be used with another example.

Example 1

A workspace device comprising:

(a) a body having a wall defining an internal volume, collapsible to fit through a laparoscopic passageway in an abdominal wall to an abdominal cavity and expand therein;

(b) a first opening defined in said body;

(c) a tool channel contiguous with said first opening and extending from said body and configured to remain, at least in part, outside of abdominal wall and sized to receive a laparoscopic tool therein therein; and

(d) said body defining an orifice configured to lie in said abdominal cavity when said body is inserted therein, said orifice sized to receive tissue with a minimal cross-sectional area that is twice a minimal cross-sectional area of said first opening, thereby defining a workspace volume to process said tissue in said cavity while said body is not collapsed, using a tool inserted through said first opening.

Example 2

A device according to example 1, wherein said tool channel comprises a rigid element which maintains a shape of said first opening and restricts advance of said tool channel into said abdominal cavity.

Example 3

A device according to example 1, wherein said orifice is directed generally laterally relative to an axis of said volume extending from said opening.

Example 4

A device according to any of examples 1-3, comprising a valve configured to seal around said tool.

Example 5

A device according to any of examples 1-4, wherein said orifice is closable.

Example 6

A device according to example 5, wherein said orifice has lips configured to close against each other.

Example 7

A device according to example 5, wherein said orifice has lips configured to close against tissue.

Example 8

A device according to any of examples 5-7, wherein said orifice seals when closed.

Example 9

A device according to any of examples 5-8, wherein said orifice has lips configured to be interlocked using a zipper.

Example 10

A device according to any of examples 5-8, wherein said orifice comprises a draw string which constricts the orifice when drawn.

Example 11

A device according to any of examples 5-8, wherein said orifice comprises a draw string which pulls lips of said orifice into a narrow aperture.

Example 12

A device according to any of examples 5-8, wherein said orifice comprises an inflatable lip, which when inflated closes said orifice.

Example 13

A device according to any of examples 5-12, wherein said orifice has a normally open state.

Example 14

A device according to any of examples 5-13, wherein said orifice has a normally closed state.

Example 15

A device according to any of examples 5-10, wherein said orifice is closable by moving said orifice out of the abdominal cavity, while said body remains in said abdominal cavity.

Example 16

A device according to example 15, wherein said wall comprises a movable thin membrane and wherein said orifice is formed in said membrane and wherein said membrane is pull able towards said channel and out of said abdominal cavity, while said workspace volume remains in said abdominal cavity.

Example 17

A device according to example 15, wherein said orifice comprises a collected sleeve, and wherein said orifice is closed by said sleeve being extended and closed.

Example 18

A device according to example 17, wherein said sleeve is long enough to extend out of said laparoscopic passageway while said body and said volume remain in said abdominal cavity.

Example 19

A device according to example 18, wherein said sleeve is configured to be extended outside of said body.

Example 20

A device according to example 18, wherein said sleeve is configured to be extended through said body.

Example 21

A device according to any of example 17-20, wherein said sleeve acts as said wall when extended, to cover said orifice.

Example 22

A device according to any of examples 17-21, wherein said sleeve is collected in a pleated configuration.

Example 23

A device according to any of examples 5-22, wherein said orifice is sealable.

Example 24

A device according to example 23, wherein said orifice comprises adhesive for providing said sealing.

Example 25

A device according to example 23, wherein said orifice comprises a suction seal between lips of said orifice.

Example 26

A device according to example 23, wherein said orifice comprises a zipperable lip.

Example 27

A device according to example 23, comprising a slider which clamps the lips of said orifice.

Example 28

A device according to any of examples 1-26, comprising at least one rigidizer configured to allow said body to resist external pressure of at least 5 mmHg without collapsing, when expanded inside said abdominal cavity.

Example 29

A device according to example 28, wherein said at least one rigidizer is configured to expand said body.

Example 30

A device according to example 28 or example 29, wherein said wall comprises a thin membrane and wherein said thin membrane is attached to and stretches over said at least one rigidizer to provide an outer surface for said wall.

Example 31

A device according to any of examples 28-30, wherein said at least one rigidizer defines a frame for said wall.

Example 32

A device according to any of examples 28-30, wherein said at least one rigidizer is insertable into said cavity after insertion of said body.

Example 33

A device according to example 32, wherein said rigidizer is inserted into said wall.

Example 34

A device according to any of examples 28-30, wherein said at least one rigidizer comprises at least one inflatable compartment.

Example 35

A device according to any of examples 28-30, wherein said at least one rigidizer is permanently attached to said wall.

Example 36

A device according to any of examples 28-35, wherein said at least one rigidizer is bendable.

Example 37

A device according to any of examples 28-35, wherein said at least one rigidizer is formed of a shape memory and/or super-elastic material.

Example 38

A device according to any of examples 28-35, wherein said at least one rigidizer includes one or more pre-defined bending points.

Example 39

A device according to any of examples 1-39, comprising at least one damage resistant section defined opposite said first opening and more resistant to damage from said tool than other parts of said wall.

Example 40

A device according to any of examples 1-40, comprising at least one sensor configured to indicate if said wall is damaged.

Example 41

A device according to any of examples 1-40, wherein said tool channel comprises a designated laparoscopic port.

Example 42

A device according to any of examples 1-41, comprising a port positioned for insertion of a tool to a side of said body.

Example 43

A device according to any of examples 1-42, wherein body has a general ellipsoid shape when expanded.

Example 44

A device according to any of examples 1-42, wherein body has an asymmetric curvature such that said body is directed down and then laterally and wherein said orifice is defined at an end of said body.

Example 45

A device according to any of examples 1-44, wherein workspace volume is large enough to receive an adult human kidney and small enough and rigid enough to not contact intra-abdominal organs when suspended from said laparoscopic channel into an abdominal cavity and containing said kidney.

Example 46

A device according to any of examples 1-45, comprising at least one suction channel extending from within said workspace volume to outside of said abdominal cavity.

Example 47

A workspace device comprising:

(a) a body having a wall defining an internal volume, collapsible to a collapsed state where said body fits through a laparoscopic passageway in an abdominal wall to an abdominal cavity and expandable to an expanded state within said cavity;

(b) said wall including at least one rigidizer, which, in said expanded state, causes said body to resist collapse by intra-abdominal forces; and

(c) said body defining an orifice configured to lie in said abdominal cavity when said body is in said expanded state in said cavity, said orifice sized to receive tissue, thereby defining a workspace volume to process said tissue in said cavity without process tissue leaking into said abdominal cavity, while said body is in said expanded state.

Example 48

A device according to example 47, wherein said at least one rigidizer is inflatable.

Example 49

A device according to example 48, wherein said at least one rigidizer comprises a plurality of separately inflatable compartments.

Example 50

A device according to example 47, wherein said wall defines at least one pocket for removably inserting said at least one rigidizer therein.

Example 51

A device according to any of examples 47-50, wherein said device, in said expanded state can withstand collapse under a condition where a pressure in said intra-abdominal cavity on one said of said wall is at least 10 mmHg greater than a pressure inside said workspace volume.

Example 52

A device according to any of examples 47-51, wherein said wall comprises a thin membrane stretched between said at least one rigidizer.

Example 53

A device according to example 52, wherein said at least one membrane is elastic.

Example 54

A device according to example 52 or example 53, wherein said at least one membrane mechanically interacts with said at least one rigidizer to set a geometry of said volume.

Example 55

A device according to any of examples 52-54, comprising at least one pusher which selectively applies a distally directed force on said at least one rigidizer to set a geometry of said volume.

Example 56

A device according to any of examples 47-55, comprising at least one adjustable elongate tensile member which mechanically interacts with said at least one rigidizer to set a geometry of said volume.

Example 57

A device according to example 56, wherein said tensile member comprises a wire located within at least one of said at least one rigidizer.

Example 58

A device according to any of examples 47-56, wherein said body defines an orifice closable to withstand intra-abdominal pressure.

Example 59

A workspace device comprising:

(a) a body having a wall defining an internal volume, collapsible to a collapsed state where said body fits through a laparoscopic passageway in an abdominal wall to an abdominal cavity and expandable to an expanded state within said cavity;

(c) said body configured to receive and enclose tissue from said abdominal cavity, of a volume of at least 300 cc;

(d) said body sealed or sealable and rigid enough to prevent collapse when an intra abdominal pressure is at least 10 mmHg higher than a pressure in said volume, when said body is in said expanded state.

Example 60

A workspace device comprising:

(a) a body having a wall defining an internal volume, collapsible to a collapsed state where said body fits through a laparoscopic passageway in an abdominal wall to an abdominal cavity and expandable to an expanded state within said cavity;

(b) said wall including at least one rigidizer, which, in said expanded state, causes said body to resist collapse by intra-abdominal forces;

(c) said body defining an orifice configured to lie in said abdominal cavity when said body is in said expanded state in said cavity, said orifice sized to receive tissue; and

(d) a collected membrane coupled to said orifice and configured to be extended to close said orifice.

Example 61

A device according to example 60, wherein said membrane is collected around said orifice.

Example 62

A device according to example 60, wherein said orifice is at an end of said body and wherein said collected membrane forms an extension to said device.

Example 63

A device according to example 60, wherein said membrane is collected to a side of said orifice.

Example 64

A device according to example 60, wherein said membrane is collected around a circumference of said device and wherein said orifice is formed in a movable part of said membrane.

Example 65

A device according to any of examples 60-64, wherein said collected membrane is long enough to extend past a proximal end of said body, when said body is in said expanded state.

Example 66

A device according to any of examples 60-65, comprising a puller coupled to said membrane and extending to outside of said body.

Example 67

A device according to example 66, wherein said puller is coupled circumferentially to said collected membrane and thereby operative to reduce a diameter of said orifice when pulled.

Example 68

A device according to example 66 or example 67, comprising a channel for passage of said puller therethrough.

Example 69

A device according to any of examples 66-68, wherein said collected membrane includes a restrictor which prevent uncollection thereof.

Example 70

A device according to example 69, wherein said restrictor comprises adhesive or a weld.

Example 71

A device according to any of examples 60-70, comprising a channel for passage of said collected membrane therethrough to outside of said body.

Example 72

A device according to any of examples 60-70, comprising a restricted diameter restrainer for passage of said collected membrane therethrough.

Example 73

A workspace device comprising:

(a) a body having a wall defining an internal volume, collapsible to a collapsed state where said body fits through a laparoscopic passageway in an abdominal wall to an abdominal cavity and expandable to an expanded state within said cavity, said volume being at least 300 cc.;

(b) at least one sensor within or on said body and configured to generate a signal indicating damage or risk of damage to said wall.

Example 74

A device according to example 73, wherein said sensor comprises a mechanical sensor.

Example 75

A device according to example 73, wherein said sensor comprises an electrical sensor.

Example 76

A device according to any of examples 73-75, wherein said wall is hollow and wherein said sensor senses a change in pressure in said wall.

Example 77

A method of processing tissue in a laparoscopic manner, comprising:

(a) inserting a collapsed workspace device in to an abdominal cavity;

(b) expanding the device to define a workspace volume therein;

(c) bringing tissue from said cavity into said device;

(d) isolating said tissue from said cavity;

(e) processing said tissue,

wherein said cavity has a same or lower pressure than said workspace volume during said processing.

Example 78

A method according to example 77, wherein said bringing is via one opening and said processing is via another opening.

Example 79

A method according to example 77, wherein said abdominal cavity is insufflated during said insertion and is not deflated until said processing is completed.

Example 80

A method according to example 77, wherein said bringing comprises bringing through an orifice and wherein said isolating comprises closing said orifice.

Example 81

A method according to example 77, wherein said isolating does not require movement of said tissue.

Example 82

A method according to example 77, wherein said isolating comprises pulling on a puller to move a part of said device relative to another part of said device.

Example 83

A method according to example 77, wherein said processing is via an opening in said device which remains outside of the body during said (a)-(e).

Example 84

A method according to example 77, wherein said processing comprises processing without said device contacting intra-abdominal organs or tissue other than an abdominal wall.

Example 85

A method according to example 77, wherein said expanding comprises inflating one or more chambers in said device.

Example 86

A method according to example 77, wherein said expanding comprises inserting a rigidizer into said device.

In accordance with one aspect of some embodiments of the present invention, a minimally invasive specimen retrieval device is provided comprising a first member movable from a first collapsed position to a second expanded position, a plurality of rigidifying members positioned internal of the first member, and an engagement member insertable into the first member, the engagement member moving the plurality of rigidifying members radially outwardly to move the first member from the first collapsed position to the second expanded position.

In some embodiments, the first member is a tubular member having a longitudinal axis and a plurality of longitudinally extending slits. The tubular member can have an opening at a proximal end and can be closed at a distal end.

In some embodiments, the first member comprises a plurality of leaves separated by slits and a cover extends over the leaves. An opening can be formed between two of the leaves for receipt of a specimen into a space within the first member. In some embodiments, the opening is selectively closable and includes for example a zip-lock mechanism or a flexible member movable proximally.

In some embodiments, the first member is substantially football shaped in the second expanded position.

In some embodiments, the engagement member is a separate element insertable into the first member; in other embodiments the engagement member is non-removably attached to the first member. In some embodiments, the engagement member is threadingly attached to the first member, wherein rotation of the engagement member advances the engagement member distally to exert a force on the rigidifying members.

In accordance with another aspect of the present invention, a minimally invasive specimen retrieval device is provided comprising a first member movable from a first collapsed position to a second expanded position and including first and second portions separable in the second expanded position. A first internal member is attached to the first portion and a second internal member is attached to the second portion. A second member is movable distally with respect to the first member to exert a force on the first and second internal members to move the first member to the second expanded position.

In some embodiments, the first member is formed of a first material and the internal member is formed of a second material, the second material being more rigid than the first material. In some embodiments, the first member includes a transparent covering material spanning a space between the first and second portions. In some embodiments, the first member includes a third portion separable from the first and second portions, and further includes an opening between the second and third portions for receipt of a specimen in a space within the first member.

In accordance with another aspect of the present invention, a minimally invasive specimen retrieval device is provided comprising a tubular member having a plurality of longitudinal slits formed therein to form a plurality of spreadable leaves. The tubular member includes a base dimensioned to remain outside an opening in a body of a patient and has an opening at a proximal end. A plurality of projections extend inwardly toward a longitudinal axis of the tubular member and a second member is advanceable within the first member to apply a force to the projections to move the leaves to a spread position to create a box-like structure.

In some embodiments, the second member is advanceable distally into the first member by a screw thread. In some embodiments, the box-like structure is shaped like a football. In some embodiments, a gap between the spread leaves is covered by a transparent material, and a receiving opening can be provided between two of the plurality of spread leaves for access to an interior of the tubular member for receipt of a specimen therein.

In accordance with another aspect of the present invention, a minimally invasive specimen retrieval device is provided comprising a tubular member having a proximal portion, a distal portion, an intermediate portion and a plurality of hinges formed at the intermediate portion. The tubular member is normally positioned in an expanded position forming a box-like structure and is insertable through a trocar in a collapsed position and upon advancement through the trocar into a body cavity moves to the expanded position.

In some embodiments, the hinges are formed by spring biasing the tubular member to the expanded position. In some embodiments, the box-like structure is football shaped in configuration. In some embodiments, the tubular member has hinges at the proximal and distal portions.

In accordance with another aspect of the present invention, a method of retrieving a specimen from a body space in a minimally invasive procedure is provided comprising the steps of 1) providing a device having a plurality of separable portions and a plurality of internal projections; 2) inserting the device through an opening in a patient into the body space; 3) expanding the device to an expanded position, the device maintained by the projections in the expanded position; 4) placing a specimen in the device; and 5) closing the device to encapsulate the specimen.

In some embodiments, the method further comprises the step of morcellating the specimen within the device. Preferably, the projections keep the walls of the device away from the specimen placed within the device.

In some embodiments, the step of inserting the device introduces the device through a trocar through an abdominal wall of the patient. In other embodiments, the step of inserting the device introduces the device through a vaginal cuff.

In some embodiments, the inside of the device is viewable via direct visualization from outside the device. In some embodiments, the step of placing the specimen in the device comprises the step of placing a specimen through a side opening in the device. The device can include a marker for facilitating directing the side opening upwards during the procedure.

In some embodiments, the step of expanding the device includes the step of advancing a member inside the device to apply an outward force to the projections. In some embodiments, the member is advanced by sliding the mem-

ber distally; in other embodiments the member is advanced by rotating the member to advance the member distally.

In some embodiments, the step of closing the device includes sliding a lock mechanism. In some embodiments, the member has a valve and a morcellator is insertable through the valve and through the member into the device.

Unless otherwise defined, all technical and/or scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the invention pertains. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of embodiments of the invention, exemplary methods and/or materials are described below. In case of conflict, the patent specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and are not intended to be necessarily limiting.

As will be appreciated by one skilled in the art, some embodiments of the present invention may be embodied as a system, method or computer program product. Accordingly, some embodiments of the present invention may take the form of an entirely hardware embodiment, an entirely software embodiment (including firmware, resident software, micro-code, etc.) or an embodiment combining software and hardware aspects that may all generally be referred to herein as a "circuit," "module" or "system." Furthermore, some embodiments of the present invention may take the form of a computer program product embodied in one or more computer readable medium(s) having computer readable program code embodied thereon. Implementation of the method and/or system of some embodiments of the invention can involve performing and/or completing selected tasks manually, automatically, or a combination thereof. Moreover, according to actual instrumentation and equipment of some embodiments of the method and/or system of the invention, several selected tasks could be implemented by hardware, by software or by firmware and/or by a combination thereof, e.g., using an operating system.

For example, hardware for performing selected tasks according to some embodiments of the invention could be implemented as a chip or a circuit. As software, selected tasks according to some embodiments of the invention could be implemented as a plurality of software instructions being executed by a computer using any suitable operating system. In an exemplary embodiment of the invention, one or more tasks according to some exemplary embodiments of method and/or system as described herein are performed by a data processor, such as a computing platform for executing a plurality of instructions. Optionally, the data processor includes a volatile memory for storing instructions and/or data and/or a non-volatile storage, for example, a magnetic hard-disk and/or removable media, for storing instructions and/or data. Optionally, a network connection is provided as well. A display and/or a user input device such as a keyboard or mouse are optionally provided as well.

Any combination of one or more computer readable medium(s) may be utilized for some embodiments of the invention. The computer readable medium may be a computer readable signal medium or a computer readable storage medium. A computer readable storage medium may be, for example, but not limited to, an electronic, magnetic, optical, electromagnetic, infrared, or semiconductor system, apparatus, or device, or any suitable combination of the foregoing. More specific examples (a non-exhaustive list) of the computer readable storage medium would include the following: an electrical connection having one or more wires, a portable computer diskette, a hard disk, a random access memory (RAM), a read-only memory (ROM), an erasable programmable read-only memory (EPROM or Flash memory), an optical fiber, a portable compact disc read-only memory (CD-ROM), an optical storage device, a magnetic storage device, or any suitable combination of the foregoing. In the context of this document, a computer readable storage medium may be any tangible medium that can contain, or store a program for use by or in connection with an instruction execution system, apparatus, or device.

A computer readable signal medium may include a propagated data signal with computer readable program code embodied therein, for example, in baseband or as part of a carrier wave. Such a propagated signal may take any of a variety of forms, including, but not limited to, electromagnetic, optical, or any suitable combination thereof. A computer readable signal medium may be any computer readable medium that is not a computer readable storage medium and that can communicate, propagate, or transport a program for use by or in connection with an instruction execution system, apparatus, or device.

Program code embodied on a computer readable medium and/or data used thereby may be transmitted using any appropriate medium, including but not limited to wireless, wireline, optical fiber cable, RF, etc., or any suitable combination of the foregoing.

Computer program code for carrying out operations for some embodiments of the present invention may be written in any combination of one or more programming languages, including an object oriented programming language such as Java, Smalltalk, C++ or the like and conventional procedural programming languages, such as the "C" programming language or similar programming languages. The program code may execute entirely on the user's computer, partly on the user's computer, as a stand-alone software package, partly on the user's computer and partly on a remote computer or entirely on the remote computer or server. In the latter scenario, the remote computer may be connected to the user's computer through any type of network, including a local area network (LAN) or a wide area network (WAN), or the connection may be made to an external computer (for example, through the Internet using an Internet Service Provider).

Some embodiments of the present invention may be described below with reference to flowchart illustrations and/or block diagrams of methods, apparatus (systems) and computer program products according to embodiments of the invention. It will be understood that each block of the flowchart illustrations and/or block diagrams, and combinations of blocks in the flowchart illustrations and/or block diagrams, can be implemented by computer program instructions. These computer program instructions may be provided to a processor of a general purpose computer, special purpose computer, or other programmable data processing apparatus to produce a machine, such that the instructions, which execute via the processor of the computer or other programmable data processing apparatus, create means for implementing the functions/acts specified in the flowchart and/or block diagram block or blocks.

These computer program instructions may also be stored in a computer readable medium that can direct a computer, other programmable data processing apparatus, or other devices to function in a particular manner, such that the instructions stored in the computer readable medium produce an article of manufacture including instructions which implement the function/act specified in the flowchart and/or block diagram block or blocks.

The computer program instructions may also be loaded onto a computer, other programmable data processing apparatus, or other devices to cause a series of operational steps to be performed on the computer, other programmable apparatus or other devices to produce a computer implemented process such that the instructions which execute on the computer or other programmable apparatus provide processes for implementing the functions/acts specified in the flowchart and/or block diagram block or blocks.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

Some embodiments of the invention are herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of embodiments of the invention. In this regard, the description taken with the drawings makes apparent to those skilled in the art how embodiments of the invention may be practiced.

In the drawings:

FIGS. **1**A and **1**B are side views of a workspace device in an open orifice state and a closed orifice state, in an abdominal cavity, in accordance with some exemplary embodiments of the invention;

FIG. **2** is a side cross-sectional schematic view of a workspace device, including various optional features, in accordance with some exemplary embodiments of the invention;

FIG. **3** is a flowchart of a method of laparoscopic treatment using a workspace device, in accordance with some exemplary embodiments of the invention;

FIG. **4**A is a top-level flowchart of a method of using a workspace device during a laparoscopic procedure, in accordance with some exemplary embodiments of the invention;

FIG. **4**B is a detailed flowchart of a method of using a workspace device during a laparoscopic procedure, in accordance with some exemplary embodiments of the invention;

FIG. **4**C is a detailed flowchart of a method of deploying a workspace device during a laparoscopic procedure, in accordance with some exemplary embodiments of the invention;

FIG. **5** is a schematic showing of the insertion of a workspace device into an abdominal cavity, in accordance with some exemplary embodiments of the invention;

FIG. **6** is a schematic showing of the effect of negative pressure difference, on leakage, in accordance with some exemplary embodiments of the invention;

FIGS. **7**A and **7**B are schematic showings of the arrangement of ribs in a workspace device with permanent rigidifying elements, in accordance with some exemplary embodiments of the invention;

FIG. **7**C is a schematic showing of a workspace device with permanent rigidifying elements and a movable membrane, in accordance with some exemplary embodiments of the invention;

FIGS. **7**D and **7**E are side cross-sectional views of a workspace device with permanent rigidifying elements and a movable membrane with a movable orifice, in accordance with some exemplary embodiments of the invention;

FIGS. **8**A and **8**B are a cross-sectional view and a side perspective view of an inflation based workspace device, in accordance with some exemplary embodiments of the invention;

FIGS. **8**C and **8**D are schematic showings of inflation based workspace devices, in accordance with some exemplary embodiments of the invention;

FIG. **8**E is a side cross-sectional view of an inflation based workspace device illustration optional breech detection and optional orifice closure by inflation, in accordance with some exemplary embodiments of the invention;

FIG. **9**A is a schematic showing of a workspace device with a sleeve extendible out of the body, in accordance with some exemplary embodiments of the invention;

FIGS. **9**B-**9**F are a series showing a workspace device with an internal sleeve extendible out of the body, at various stages of use, in accordance with some exemplary embodiments of the invention;

FIG. **9**G is a side view of a workspace device with a lateral orifice having extendible lips, in accordance with some exemplary embodiments of the invention;

FIGS. **9**H and **9**I are views of a curved workspace device with a lateral orifice having extendible lips, in accordance with some exemplary embodiments of the invention;

FIG. **9**J shows a curved workspace device with a purse-string mechanism for orifice closure, in accordance with some exemplary embodiments of the invention;

FIG. **9**K shows a curved workspace device with an extended lip of an orifice passed through a closure channel within the device, in accordance with some exemplary embodiments of the invention;

FIG. **9**L shows a curved workspace device with an extended lip of an orifice configured for passing through a closure channel on an outside of the device, in accordance with some exemplary embodiments of the invention;

FIG. **9**M shows a workspace device with an extended lip of an orifice configured for passing through a restrictor, for closure of the orifice, in accordance with some exemplary embodiments of the invention;

FIG. **9**N shows a workspace device with an extended lip of an orifice configured for being pulled outside the device and out of the body, for closure of the orifice, in accordance with some exemplary embodiments of the invention;

FIG. **10**A is a side cross-sectional view of a workspace device having a side opening for tool insertion, in accordance with some exemplary embodiments of the invention;

FIG. **10**B shows a workspace device with a sliding closure, in accordance with some exemplary embodiments of the invention;

FIG. **10**C is a detail view of a adhesive sealing mechanism, in accordance with some exemplary embodiments of the invention;

FIG. **10**D is a side view of a workspace device using tensile members within rigidifying members for controlling a shape of the device, in accordance with some exemplary embodiments of the invention;

FIG. **11** is a perspective view of an embodiment of the device of the present invention, the device shown in the collapsed position;

FIG. **11**A is an exploded view of the projections of FIG. **11**;

FIG. **12**A is a cross-sectional view of the device of FIG. **11** shown in the collapsed configuration, and shown inserted through a trocar into the body cavity;

FIG. **12**B is a cross-sectional view of the device of FIG. **11** shown in the expanded configuration;

FIG. **13** is a perspective view of the device of FIG. **11** shown prior to advancement through a trocar positioned in the abdominal wall to retrieve a specimen from the abdominal cavity;

FIG. **14** is perspective view of the device of FIG. **11** shown inserted in a collapsed configuration through the trocar into the abdominal cavity;

FIG. **15** is perspective view similar to FIG. **14** showing the expander positioned within the tube and the device in the expanded configuration;

FIG. **16** is a close up view of one embodiment of a closing mechanism;

FIG. **17** is perspective view similar to FIG. **15** showing a grasper inserted through another trocar port for sealing the device once the specimen is placed within the device;

FIG. **18** is perspective view similar to FIG. **16** showing the grasper sliding the lock of the locking mechanism of FIG. **16** to seal the device and further showing a morcellator prior to introduction through the trocar into the device;

FIG. **19** is a perspective view of an alternate embodiment of the device having a string actuable for sealing the device;

FIG. **20** is perspective view similar to FIG. **18** showing the morcellator inserted into the device for breaking up the specimen within the device;

FIG. **21** is perspective view of similar to FIG. **19** showing the morcellator and expander being removed from the device, and the device in the collapsed position;

FIGS. **22**A-**22**C are perspective views of an alternate embodiment of the device having a rotatable expander for expanding the device; and

FIGS. **23**A-**23**C are perspective views of another alternate embodiment of the device of the present invention.

DESCRIPTION OF SPECIFIC EMBODIMENTS OF THE INVENTION

A broad aspect of some embodiments of the invention relates to a workspace device, which may be inserted into the body (e.g., a body lumen such as the abdominal cavity) and used for processing body tissue therein, while inside the body. Optionally, the processing comprises morcellating or other size reduction method applied to tissue, prior to tissue removal from the body, such that the workspace device ultimately acts as a retrieval device.

An aspect of some embodiments of the invention relates to a workspace device including at least one rigid or rigidifiable portion. In some exemplary embodiments of the invention, the portion is used to define the workspace inside the body. In some exemplary embodiments of the invention, the use of rigid portions allows the workspace to resist collapse due to pressure from organs or fluid (such as intra-abdominal gas used for insufflation) inside the body.

In some exemplary embodiments of the invention, the device is made more rigid and/or changes in shape to a more volumetric form when in the body and is maintained in such larger volumetric form during sealing thereof and/or processing of tissue therein.

In some exemplary embodiments of the invention, sealing comprises closing in a way which avoids pressure loss. Optionally or alternatively, sealing comprises closing in a way which avoids tissue cross-contamination.

In some exemplary embodiments of the invention, the device is defined by a wall with a plurality of rigid elements defining the wall. Optionally, flexible material is provided between the rigid elements. It should be appreciated that "rigid" does not mean hard. Rather, it means stiff enough to resist typical pressures and forces expected during an operation, for example, the device may be stiff enough to maintain its shape with less than 10% change in volume in an ambient environment with a pressure above the device pressure such as 5 mmHg, 10 mmHg, 20 mmHg, 30 mmHg or intermediate or higher pressure. Optionally, change in volume is defined by change in total volume or by the degree of spatial overlap between the volume with and without pressure, as a percentage of the original volume. Optionally, the rigid elements are resilient and may be deployed deformed, optionally formed of shape memory and/or super-elastic material. Optionally or alternatively, the rigid elements are deformed by deployment and/or include predefined folding regions for deployment.

In some exemplary embodiments of the invention, at least 20%, 40%, 60%, 70% or smaller, intermediate or larger percentages of the surface of the device inside the abdominal cavity do not have an underlying rigid or rigidizing element.

In some exemplary embodiments of the invention, rigidization is provided by inflation of one or more chambers formed in the device. Optionally, the device, at least in part, is formed of a double layer of fluid or gas impermeable material, which are sealed to each other to define chambers and, optionally, fluid provision pathways.

In some exemplary embodiments of the invention, the chambers or other types of rigid elements are interconnected to each other (or not) and flexible material spans spaces therebetween in a way which avoids a single point of failure. For example, a plurality of rigidization compartments or elements are provided and failure of a single one or tearing of a thin section between two such compartments, does not cause failure of the device as a whole. In some exemplary embodiments of the invention, the rigid elements are interconnected to the membrane, preventing the propagation of a tear past a neighboring rigid element. In some exemplary embodiments of the invention, each rigid element is independently fallible. For example, if the rigid elements are inflatable chambers, at least some chambers have a separate valve and/or inflation pathway, so failure of one does not mean failure of all. If the ribs are inserted in channels, the channels may have separate welds.

In some exemplary embodiments of the invention, the membrane includes one or more threads or other flexible strengthening elements, and that lie between ribs, so as to slow or prevent propagations of tears past the strengthening elements.

In some exemplary embodiments of the invention, if a first workspace device tears or otherwise fails, a second workspace device may be inserted (e.g., through another incision) and the first workspace device inserting into an orifice of the second device. The second workspace can be used as a patch (e.g., its lips **202** closing over the neck part of the first workspace device). Alternative, the contents of the first device are emptied into the second device and the first device removed and the second bag sealed and used to process tissue.

In some exemplary embodiments of the invention, the device is rigidized in steps, for example, a first rigidization of one or more components is used for deployment into the body. A second rigidization of one or more components is used for deployment and/or a third rigidization is used to close and/or seal an opening through which tissue is inserted into the workspace. In some exemplary embodiments of the invention, steps are provided by sequential inflation of different chambers, for example, using an automated inflator, or by manual inflation of each one, when desired. In some exemplary embodiments of the invention, one of the steps comprises retracting tensile element, thereby modifying the shape of a rigidifying element of the device.

In some exemplary embodiments of the invention, rigidization of the workspace device is provided by insertion of rigid elements and/or by bending of existing rigid ele-

ments (e.g., at pre-defined bending areas or hinges). In some embodiments of the invention, the device defines channels (e.g., between welded layers of thin material), into which such rigid elements may be inserted.

In some exemplary embodiments of the invention, rigidization is provided by releasing (e.g., by sheath retraction) of existing rigid elements to expand to a pre-defined state. In some embodiments of the invention, rigidization is provided by interlocking of rigid elements, optionally after rearrangement thereof, for example, using a structure similar to that of an umbrella to lock together rigid elements that define a dome shape. Optionally or additionally, the thin membrane between the elements serves are part of the rigidifying structure, again, for example, as in an umbrella, by acting as a tensioning element. In some exemplary embodiments of the invention, the membrane is elastic and resists, to some extent, the bending of the rigid elements.

A potential advantage of such rigidization, in some embodiments thereof, is that the workspace can have a lower internal pressure than the abdomen and not collapse.

Another potential advantage of rigidization, in some embodiments thereof, is protection of organs in the body from forces applied inside the workspace.

Another potential advantage of rigidization, in some embodiments thereof, is allowing the workspace to be open to the body lumen while maintaining its shape. It is a particular feature of some embodiments of the invention that the rigidization elements may be maintained in place and rigidity during tissue processing, at least such elements as maintain the shape of the workspace.

Another potential advantage of rigidization is that the thin membrane is protected from being inadvertently processed by an inserted morcellator. In some embodiments of the invention, the thin membrane between the rigidization elements deflects inwardly (e.g., due to external pressure) less than 10 mm, 5 mm, 3 mm or intermediate distances, relative to a surface of a minimal convex object interconnecting the rigid elements.

An aspect of some embodiments of the invention relates to providing a negative pressure differential (or at least no significant positive differential) between an inside of a workspace and the surrounding tissue while the workspace is expanded. In some exemplary embodiments of the invention, this differential is made possible by the existence of one or more rigid elements maintain the shape of the workspace against such pressure difference.

In some exemplary embodiments of the invention, the provision of the pressure differential compensates for any leaks in a sealing and/or in a body of the workspace device, and prevent or reduce leakage of tissue or tissue parts back into the body lumen, once it had been provided into the workspace for processing.

A potential advantage of such negative pressure, in some embodiments thereof, is the avoidance of over-interfering with a surgical procedure, as neither insertion, nor deployment, nor usage, nor removable of the workspace device necessarily require abdominal decompression in some embodiments.

In some exemplary embodiments of the invention, there is equal pressure in the workspace and the body. This may be provided by the workspace including one or more apertures which are gas permeable and cell impermeable. Optionally, the apertures are provided in the form of a membrane which has these properties.

In some embodiments of the invention, the workspace device may be inflated after sealing thereof.

An aspect of some embodiments of the invention relates to a workspace device with a tissue entry orifice, which is closed after the tissue is inserted into the workspace. In some exemplary embodiments of the invention, the orifice is sealed, to prevent tissue particles from leaving the workspace back to the body lumen. It is a particular issue of some embodiments of the invention that the tissue entry office may coexist with an additional orifice open to the outside of the body.

In some exemplary embodiments of the invention, the orifice is in the form of a side opening in the workspace. In some exemplary embodiments of the invention, the orifice is formed between rigid or rigidifiable parts of the workspace device.

In some exemplary embodiments of the invention, the orifice is between 10% and 30% of an outside surface area of the workspace, of the portion intended for intrabody locating. In some exemplary embodiments of the invention, the orifice is significantly larger, for example, between 30% and 50%, 70, 80% or intermediate or greater percentages. In some embodiments of the invention, these percentages are of a surface of a geometrical object defined by the workspace. For example, the workspace may function as a frame, and once the organ or other tissue is placed therein, the frame is covered with a covering to provide sealing against the body lumen.

In some exemplary embodiments of the invention, the orifice has a normally open state and is closed when needed. Optionally or alternatively, the orifice has a normally closed state and can be opened when needed.

In some exemplary embodiments of the invention, the orifice is in the form of a valve (e.g., a flap valve), optionally supporting insertion of tissue into the workspace, but not egress out of the workspace. In some exemplary embodiments of the invention, the use of a valve is made possible by the rigidifying elements which maintain the shape of the workspace and/or by dedicated rigidifying elements associated with the valve itself and which may provide support to the valve.

In some exemplary embodiments of the invention, the orifice is designed to be sealed. Optionally, the orifice is designed to be sealed to itself or other part of the workspace device. Optionally or alternatively, the orifice is designed to be removed from the body (while the workspace remains in the body, thereby sealing the orifice from the body lumen. Optionally or alternatively, the orifice is designed to seal against tissue, for example, allowing a portion of tissue being treated to remain in the workspace, while connected parts of the tissue remain outside the workspace. This may be useful for draining cysts, where the cyst is brought into the workspace, drained and possibly ablated, while not overly damaging the rest of the tissue. This may allow the tissue damage to avoid damage (e.g., cutting) otherwise possibly necessitated by dealing with a bloated cyst.

In some exemplary embodiments of the invention, closing of the orifice and/or sealing thereof are by manipulations performed from outside the body, for example, pulling on a drawstring which extends to outside the body. Optionally, the drawstring is used for one or more of closing the orifice, sealing the orifice, rotating the workspace and/or extending the orifice out of the body.

In some exemplary embodiments of the invention, closing the orifice comprises closing a zipper. In some exemplary embodiments of the invention, closing the orifice comprises pulling a part of the workspace surface towards the outside of the body. In some exemplary embodiments of the invention, closing the orifice comprises folding a portion of the

surface over the workspace. In some exemplary embodiments of the invention, closing comprises sliding or rotating one part of the workspace device relative to another. In some exemplary embodiments of the invention, sealing is not provided, for example, due to existence of a negative pressure differential between the workspace and the body lumen, which may sufficiently reduce or prevent tissue escape from the workspace.

In some embodiments of the invention, the workspace is closed, sealed and/or otherwise manipulated using a laparoscopic tool inserted from outside the body, optionally through its own port, and which access the outside of the workspace.

In some exemplary embodiments of the invention, the closure and/or sealing mechanism, when sealed and/or closed, is concave or flat and/or otherwise lacks protrusions away from the workspace device surface. This may help avoid parts of the workspace device snagging on body parts or medical tools during removal. Optionally, the closure and/or sealing mechanism have a minimum radius of curvature above 3 mm, 2 mm or 1 mm. Optionally or alternatively, the mechanism may or extends less than 3 mm, 2 mm, 1 mm, outwards from a surface of the workspace. Optionally or alternatively, such projection, and/or greater projection is of a material and/or geometry which does not damage tissue by contact thereof under small forces. It is noted that the parts of the device designed for intra-abdominal position may have such properties in addition to or instead of just the sealing and/or closing mechanism.

In some exemplary embodiments of the invention, the sealing mechanism comprises adhesive. Optionally, the adhesive is covered and is revealed, for example, by removing a cover layer, for example, using a drawstring. Optionally or alternatively, the adhesive is release from a reservoir using a zipper mechanism and/or by pinching together of lips of the orifice, for example, using a grasper.

In some exemplary embodiments of the invention, sealing is provided, at least in part by folding an extension of lips of the orifice.

In some exemplary embodiments of the invention, sealing is provided, at least in part by radially contracting together an extension of lips of the orifice, for example, using a ring.

In some exemplary embodiments of the invention, sealing is provided, at least in part by pulling on a purse-string suture surrounding the orifice.

In some exemplary embodiments of the invention, sealing is provided, at least in part by applying suction by the lips to a surface in contact with the lips.

In some exemplary embodiments of the invention, the lips extend away from the rest of the device, for example, between 1 and 30 mm, for example, between 2 and 10 mm. Optionally, such extensions are soft. In some exemplary embodiments of the invention, the extension is much larger, for example, above 30 mm, above 50 mm, above 100 mm, above 200 mm, or intermediate in size.

In some exemplary embodiments of the invention, after closure, a small gap remains. Optionally, this gap is closed by inserting a plug thereinto.

In some exemplary embodiments of the invention, the tissue is pushed in to the orifice, for example, using the morcellator and/or using a gripper or other tool. In some exemplary embodiments of the invention, the tissue is pulled into the workspace, for example, by a morcellator, gripper or other tool extending into one aperture of the workspace and out the orifice. In one example, the morcellator applies vacuum to grasp the tissue during manipulation thereof. In another example, the orifice is larger than 180 degrees in extent and the workspace device or at least a membrane portions thereof is deployed around the tissue.

An aspect of some embodiments of the invention relates to a workspace device with two openings, one for insertion of tissue and one for insertion of a morcellator or other tissue processing tool. Optionally, the two openings remain at least 2 cm apart during use of the device. In some exemplary embodiments of the invention, one opening is to the side of the workspace and one opening is at a top of the workspace (e.g., where it is inserted into the body). In some embodiments of the invention, one opening extends to the outside of the body also while tissue is inserted into the workspace. Optionally or additionally, the locations of at least one opening relative to the workspace is maintained using a rigidifying element which interconnects them.

In some embodiments of the invention, an opening which is intended for tools for processing the tissue, for example, a morcellator, always extend to outside of the body.

It is a particular feature of some embodiments of the invention that a different opening is used for inserting the tissue into the workspace than the one used for inserting tools, such as a morcellator.

It is a particular feature of some embodiments of the invention that no access is made to the tissue in the workspace from inside the abdominal cavity (or other body lumen) after the tissue ingress orifice is closed.

In some exemplary embodiments of the invention, the workspace is in the form of a sleeve, with one opening at either end of a generally tubular shape (straight or bent). Optionally, in use, the tissue ingress opening is closed and optionally removed from the body, while the tissue and the space of the workspace device, remain in the body. Optionally, a cord is used to both close and draw this ingress opening out of the body. In some embodiments of the invention, the part of eth sleeve near the orifice is folded or otherwise compacted to a ring surrounding the orifice.

In some exemplary embodiments of the invention, one opening extends out of the body, also while the tissue is provided into the workspace. Optionally, this opening is used for insertion and retraction of the morcellator and/or other tissue processing tool. In some embodiments, both openings remain inside the body and are optionally both sealed during tissue processing.

An aspect of some embodiments of the invention relates to safety of using a workspace device, especially for morcellation and/or manipulation using hard-tipped tools, such as grippers.

In some exemplary embodiments of the invention, the safety comprises protecting the workspace device itself from being damaged by the tools being used, such as the morcellator or gripper. Optionally, a part of the workspace surface where such tools are expected to contact (e.g., opposite a tool entry opening), is protected by a mesh, optionally spaced apart from the wall and/or by thickening the wall at such a part. Optionally or additionally, the sensitive parts of the device (e.g., thin membranes) are maintained in a taunt and/or concave configuration relative to the morcellator so that they cannot be inadvertently processed thereby.

In some embodiments of the invention, the workspace device includes one or more sensors to detect damage or risk of damage thereto. Optionally, the sensor is associated with the volume of the device, for example, a pressure sensor which can detect changes in volume that indicate a leak. In some embodiments of the invention, the senor is associated with the surface of the device, for example, a conductive mesh which can be used, e.g., using impedance measure-

ment, to detect a proximity of a metal tool tip to the surface. Optionally or additionally, the sensor detects a mechanical property of the surface itself, for example, strain or tears. In some embodiments of the invention, the sensor is in the form of a conductive mesh or an array of mechanical sensors embedded in the wall. In some exemplary embodiments of the invention, the sensor comprises a tube interconnecting inflatable chambers of the device with an indicator outside the body. Failure of an internal wall of the device will reduce pressure in one or more chambers, leading to reduction of pressure in the tube, which can be seen on the indicator, for example, electrically or mechanically. Optionally, a circuitry is attached to the tube and includes or is connected to a user interface for displaying an alert to a user. Optionally or alternatively, such a tube may carry tissue or blood to outside the body, also providing a visual indication.

In some exemplary embodiments of the invention, the safety comprises prevention failure of the procedure. For example, the workspace device, may be set up to fail gradually (e.g., a hole formed) rather than catastrophically (all the innards of the workspace volume spray out). For example, the device may include a plurality of independently fallible rigidifying components, such that only one fails at a time, rather than the entire structure. Optionally, at least 4, 6, 8 or more such stand-alone components are provided. Optionally or alternatively, when in the form of a thin membrane connected between the elements, the elements are interconnected so that a tear (or other failure) in the membrane does not cause the elements to move apart and enlarge the tear.

In some exemplary embodiments of the invention, the safety comprises resilience in face of damage or manufacturing problems of the workspace device. Optionally, the provision of lower pressure in the workspace than in the abdomen and/or provision of continuous suction out of the workspace prevents any surface integrity problems from allowing tissue debris to exit the workspace into the body. Optionally or alternatively, a suction source (e.g., a tube extending into the workspace, optionally to a bottom thereof) is provided to extract, optionally continuously, tissue fragments, so that any leak will have less material to leak out. Optionally or alternatively, blood coagulator or absorbent material may be provided in the workspace and/or on lips of the orifice and/or near the orifice and/or between layers of the wall of the device (e.g., to be activated if a wall is breached).

In some exemplary embodiments of the invention, safety comprises safety of other, nearby organs. Optionally, the workspace is made soft enough and/or has a thick enough wall (e.g., a double inflated wall or sponge filled wall), so that tools moving inside the workspace device are less likely to damage nearby organs through the wall of the device.

In some embodiments of the invention, the wall of the device is a double wall, which is optionally filled with, for example, gas, fluid or a foam material, and which can provide softening of the outer wall and/or resistance to force and/or tool transmission therethrough. Optionally, the wall is connected to a vacuum source, so that damage to a surface of the wall, causes tissue particles to be sucked away, rather than potential leak out of the device.

In some exemplary embodiments of the invention, safety relates to user safety. In some exemplary embodiments of the invention, a seal is provided between the morcellator and the workspace, for example, in the form of a valve as part of the workspace device and outside the body or on the path to outside the body, through which valve the morcellator is inserted and removed. Optionally, the same valve or an additional valve is used for inserting and/or removing a different tool, such as a gripper or other tissue manipulator, used in tissue processing.

An aspect of some embodiments of the invention relates to the workspace volume being operative to be used for working on tissue, rather than just for tissue retrieval. In one example, the workspace is transparent or includes one or more transparent windows on the body or in a valve thereof allowing viewing of its inside from outside thereof. In another example, the workspace includes one or more valves for insertion and/or removal of tools for tissue processing, from within the abdominal cavity.

An aspect of some embodiments on the invention relates to integrating the use of a morcellator into laparoscopic or other minimally invasive procedures. In some exemplary embodiments of the invention, the morcellator includes a laparoscopic port, for example, a port into the workspace volume or to a side thereof, thereby controlling intra-abdominal pressure (for abdominal laparoscopy), while allowing tool insertion and removal. Optionally, this allows the workspace to be inserted early in the procedure and be physically collocated with a gripper or other tool. Optionally, the gripper passes through the workspace volume itself. Optionally, the workspace volume is axially collapsed during such deployment until a workspace volume is needed. Optionally, this allows tissue to be pulled into the workspace device after deployment thereof.

In some embodiments of the invention, a tool inserted through a different port into the body lumen is used to access the workspace and/or the inside of the workspace volume, optionally through a valved opening in the workspace surface.

In some embodiments of the invention, the outside surface of the device is marked, for example, with a grid or with indications where gripping is safe, to assist in interaction with tools during a laparoscopic procedure.

An aspect of some embodiments of the invention relates to a workspace device which has an end adapted to be attached to an abdominal wall and a laterally directed orifice for inserting tissue into the device. In some exemplary embodiments of the invention, the orifice is smaller than a maximal cross-section of the device. Optionally or alternatively, the orifice remains in the cavity while the tissue is processed. Optionally or alternatively, the device includes an opening where it is adapted for attachment to the abdominal wall, for insertion of a tool therethrough.

In some exemplary embodiments of the invention, a lateral orifice is an orifice whose axis lies along a line no more than 30 degrees off from a perpendicular to a perpendicular to the abdominal wall, where the device is attached. The orifice axis may be defined as the perpendicular to a plane which most closely approximates the perimeter of the orifice (e.g., using RMS distance).

An aspect of some embodiments of the invention relates to a damage indicator for a laparoscopic bag, in accordance with some embodiments of the invention. Optionally, the indicator comprises a channel connecting a pressurized part of the bag to a location outside the body. Change in pressure in the bag, which can indicate damage thereto, can be indicated, for example, visually, by a collapse or expansion or other movement of an indicator attached to the channel. Optionally or alternatively, a pressure sensor is used. Optionally or alternatively, a UI circuit is used to generate an alert, for example, a colored LED, or a sound. This indicator may be used for bags designed to be used at a pressure above, below or even at that of the abdominal cavity.

Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not necessarily limited in its application to the details of construction and the arrangement of the components and/or methods set forth in the following description and/or illustrated in the drawings and/or the examples, if any. The invention is capable of other embodiments or of being practiced or carried out in various ways.

Referring now in detail to the drawings wherein like reference numerals identify similar or like components throughout the several views, various embodiments of the laparoscopic specimen retrieval device of the present invention are illustrated. The devices are designed to expand to a box-like structure to create a protected space within the patient's body. This enables the tissue particles to be isolated for removal, and in certain applications, enables morcellation of the particles without the risk of scattering the tissue within the patient's body. The configuration and rigidity of the device maintains its wall away from the specimen placed therein, reducing the risk of the wall of the device being cut by the morcellator and leaking contents from the device into the body cavity.

Exemplary Workspace Device

FIGS. **1**A and **1**B are side views of a workspace device **120** in an open orifice state (FIG. **1**A) and a closed orifice state (FIG. **1**B) in an abdominal cavity **122**, in accordance with some exemplary embodiments of the invention.

FIG. **1**A shows a schematic workspace device **120** inside an abdominal cavity **122**, and inserted through an aperture **128** in an abdominal wall **124**.

A tissue orifice **130** is shown in a body surface **132** of workspace device **120**. In some embodiments of the invention, tissue is inserted into an internal volume **134** of workspace device **120** through orifice **130** for later processing. FIG. **1**B shows device **120** in a closed orifice configuration, where orifice **130** is closed, allowing, for example, processing of tissue inside device **120** without contaminating tissue in abdominal cavity **122**.

In some embodiments of the invention, processing includes inserting a morcellator or other tool through an opening portion **126** of device **120**. Optionally, opening **126** includes or is fitted in a laparoscopic port. Optionally, opening **126** includes a valve, for example, inside volume **134** and/or outside of volume **134** (possibly as part of the laparoscopic port), but configured to press inward one or more flexible extensions of surface **132** against any tool inserted into device **120** through opening **126**. In some embodiments of the invention, opening **126** includes a rigid structure (e.g., a laparoscopic port) which maintains aperture **128** open.

As will be explained below, in some embodiments, closing and/or sealing of orifice **130** is by extending a portion of the opening outside of the body. It is noted, that opening **126** optionally remains at and in aperture **128** throughout the usage of device **120**.

FIG. **2** is a side cross-sectional schematic view of a workspace device **220**, including various optional features, in accordance with some exemplary embodiments of the invention. Exemplary use of some of the optional features will be described in more detail in later parts of this document.

In some embodiments of the invention, device **220** has a body formed of a thin membrane (surface **232** which acts as a wall) stretched out between or bridging one or more rigidifying elements **218**, **222**. As shown, one or more vertical rigidifying elements **218** may be provided. Optionally or additionally, one or more horizontal and/or circumferential (e.g., longer than 30%, 50%, 80% or intermediate percentages of the circumference of device **220** where they are located) rigidifying elements **222** may be provided. Optionally or additionally, one or more helical elements or other shapes which extend in both vertical and horizontal directions, may be used.

A channel **219** is shown, which is adapted for later insertion of a rigidifying element thereto. Optionally, the channel is formed by welding of a layer to the thin membrane. In some embodiments, a rigidifying cage or structure is inserted into volume **234** without a dedicated channel.

An orifice **230** is shown, optionally with a vertical orientation and which includes a lip **202**. In some embodiments of the invention, lip **202** includes one or more rigidifying member for shaping orifice **230** (e.g., and setting it to normally open or normally closed states). Optionally or additionally, lip **202** includes a closure and/or sealing mechanism (e.g., a zipper as described for example in FIG. **16**). Optionally or additionally, lip **202** includes a compacted sleeve, for example an extension of membrane **232**, for example, as may be used for a sleeve embodiment of FIGS. **9**A-N.

Optionally, a manipulation element **204**, for example, mechanical pull element is provided to manipulate lip **202**. In one example, element **204** is a wire which forms an extension of a purse-string suture for closing orifice **230**. In another example, element **202** serves to pull a zipper shut. In another example, element **202** when manipulated, releases adhesive to adhere lips **202** together. In embodiments where the rigidifying elements are inflatable or where lips **202** include an inflatable compartment, element **204** may be used to deliver fluid, such as gas or liquid, optionally using a syringe.

Some parts of surface **232** may be thickened **206**, or be double walled.

In some embodiments of the invention, a protective layer **224**, for example a mesh, is provided, optionally spaced apart from wall **232** of volume **234**, to protect wall **232** from mechanical damage.

In some embodiments of the invention, additional material, such as a coagulant **226** are attached to inside surface **232**. Alternatively, such materials may be added later.

In some embodiments of the invention, volume **234** includes a connection to a suction source **210**, for example, a pump. Optionally, the connection comprises a channel **208** which may extend to a bottom of the volume (e.g., where fluid is expected to collect gravitationally) and/or into a double layered wall section **206**.

In some embodiments of the invention, device **220** includes a sensor circuitry **216** for processing signals received from device **220**, for example, from a sensor **212**, such as a pressure sensor. Optionally, circuitry **216** generates an alert, for example, if pressure increases indicating a wall breech and/or sends data to a processing unit (not shown), for example a workstation. Optionally, a planar sensor **214** is used and mounted to or in wall **232**. In one example, sensor **214**, which may be in the form of a conductive mesh or grid, is operated as an impedance sensor which detects the proximity of metal tools and/or objects which deform electric fields. Optionally or additionally, sensor **214** includes one or more stain sensors for detecting a strain on wall **232**, especially strain as may be caused by contact of a tool thereon. Optionally or additionally, sensor **214** includes one or more (conductive) tear fuse sections which tear before or with wall **232** and generate an indication of damage thereto (e.g., when their electrical resistance goes up).

In some embodiments of the invention, there is provided a chamber **228** for an optical instrument for viewing operations inside device **220**. Optionally, a channel **240** extends from outside the body to chamber **228** and may be used to insert a camera, optionally in the form of an endoscope. Optionally, chamber **228**, which may be elastic and/or flexible allows bending and/or rotation of a tip of such an imager, to control viewing field thereof.

Referring now to an opening portion **226** of device **220**, which is optionally configured to remain partly outside and partly across abdominal wall **124** through the use of the workspace, including deployment thereof. In some embodiments of the invention, opening **226** includes a rigid frame **242**, which may be a part of a laparoscopic port and/or otherwise maintain open the point of insertion through abdominal wall **124**.

In some exemplary embodiments of the invention, wall **232** extends into opening **226** (outside or inside of frame **242**) as a neck/tube **246** so as to provide a continuous covering for volume **234**. In some embodiments of the invention, the top (e.g., proximal side) of tube **246** is sealed with a valve **244** which optionally closes around a morcellator (or other tools) when inserted and which may prevent spraying of tissue from device **220** into the room. In some embodiments of the invention, one or more additional openings **250** into volume **234**, are provided, optionally valved. In some embodiments of the invention, a valved opening **248** is provided between tube **246** and frame **242** and which may be used for inserting tools which can access the outside of workspace device **220**. Optionally, valve **248** is compressible to a more flat configuration when a larger tool is inserted into tube **246**, for example, the walls of tube **246** being properly sized and/or being elastically compliant.

A laparoscopic port is not shown for brevity in many of the figures herein. Also, it is noted that while some parts may be shown as entering abdominal wall **124** through a separate opening than used for the device, this is sometimes done to more easily distinguish the different objects entering the body, but a single hole may be used. Similarly, the wound in the abdominal wall is generally shown open, even when it would naturally collapse on the device. Also similarly, the thickness of the abdominal wall is schematic and an actual patient may have a thicker wall, due, for example, to subcutaneous fat layers. Optionally, neck **246** is selected to be long enough to cross this distance and/or any fixed tubular portion of a port, if used.

Exemplary Laparoscopic Procedure using Workspace Device

FIG. **3** is a flowchart of a method of laparoscopic treatment using workspace device **220**, in accordance with some exemplary embodiments of the invention.

At **302**, the procedure is planned, for example, removal of a kidney, a uterus, a portion of GI tract or a tumor. As part of the planning a particular workspace device may be selected and/or an insertion location therefore planned. For example, if a procedure involves removing one large organ (e.g., a kidney) and several small pieces of tissue, a suitably sized device **220** may be selected. Optionally or additionally, the shape of the deployed workspace is chosen according to a location within the abdomen and nearby tissue and/or a tissue insertion direction, for which it will be used. Such choosing and selecting may also be done later in the procedure.

At **304** the abdominal cavity (if that is the body lumen treated) is optionally insufflated. Insufflation may also be done at a later stage, optionally following standard guidelines for laparoscopic procedures. It is noted that in some embodiments of the invention insufflation practices are not changed due to use of workspace device **220**, as compared to a procedure without tissue removal.

At **306** and **308** a camera and/or other tools, maybe inserted, for carrying out the procedure, for example, following standard methods of laparoscopic surgery. In some exemplary embodiments of the invention, one or more tools may be inserted into the abdominal cavity through device **220**, so device **220** will be inserted first.

FIGS. **11-18** show an exemplary embodiment of a workspace device **10**, including exemplary usage steps in FIGS. **13-21**.

At **310**, a workspace device is inserted, for example, during an existing or through a dedicated incision in the abdominal wall. In some embodiments, the workspace device is inserted at the beginning of the procedure long (e.g., 10-15 minutes or more) before the workspace device is needed. In some embodiments of the invention, the workspace device is maintained in a less obtrusive configuration until it is needed. Alternatively, device **220** is inserted nearer to when it is needed, for example, just before tissue is cut away or after it is cut away, for removal thereof. FIGS. **13-15** show insertion and deployment of a workspace device **10** (called below a retrieval device) through a laparoscopic port **11**.

At **312** tissue is manipulated, for example, selected or cut away from other tissue. In FIG. **13** a tissue **8** is already separated from other tissue.

At **314**, the selected tissue is placed inside volume **234**, for example, pulled in or pushed in, using a gripper. FIG. **17** shows tissue **8** inserted into device **10**.

At **316**, the issue is processed, for example macerated. In some embodiments of the invention, the abdominal cavity remains insufflated during this processing and is not decompressed for insertion or manipulation of device **220**. FIGS. **18** and **20** show the insertion of a morcellator **110** into device **10** to process tissue **8**.

At **318** workspace device **220** is removed from the body with the processed tissue. In some embodiments, the macerated tissue is removed first. FIG. **21** shows a collapsed workspace device **10** with morcellated tissue therein during removal thereof.

At **320**, the procedure may continue (e.g., suturing, implanting).

Exemplary Usage of a Workspace Device

FIG. **4**A is a top-level flowchart of a method of using a workspace device during a laparoscopic procedure, in accordance with some exemplary embodiments of the invention. FIG. **4**B is a detailed flowchart of a method of using a workspace device during a laparoscopic procedure, in accordance with some exemplary embodiments of the invention. Referring first to FIG. **4**A.

At **402**, workspace device **220** is deployed, for example as will be detailed below;

At **404**, tissue, for example, an organ or other tissue makes its way into working volume **234** of workspace device **200**.

At **406**, an orifice through which tissue entered volume **234** is closed.

At **410**, the enclosed tissue is processed.

At **412** workspace **220** is removed from the body.

Referring now to FIG. **4**B.

At **422**, device **220** is inserted into the body. FIG. **5** is a schematic showing of the insertion of workspace device **220** into abdominal cavity **122**, in accordance with some exemplary embodiments of the invention. Tissue to be processed **508** is shown as being free in cavity **122**, though it may be attached to tissue and/or may be held by a tool, such as a

gripper (not shown). In the example shown, device **220** is mounted in a delivery system **502**, for example, a plunger, which attaches to a port **506** or, alternatively is fit into opening **128** in abdominal wall **124**. In some exemplary embodiments of the invention, delivery system **502** includes a dedicated insertion port (e.g., **506**), which optionally detaches from device **502** after device **220** is inserted into abdominal cavity **122**.

In some embodiments of the invention, opening **128** is a dedicated opening. Alternatively, it is an opening previously or later used for a different laparoscopic tool. Optionally, the opening is expanded if device **220** needs a larger opening than the tool. Optionally, the opening is in the umbilical region or from a side of the abdomen.

At **424**, device **220** is sealed to opening **128**. This may be needed, if device **220** does not include its own frame **242** for opening **128**. It is noted that in some embodiments, parts of membrane **232** are pulled out of the body, while a frame portion of device **220**, if any, and/or rigid portion **242**, if any, may remain within. In some exemplary embodiments of the invention, device **220** is inserted through a laparoscopic port, which may include a seal. The term "laparoscopic channel" is used to generally describe any type of opening in the abdominal wall, through which device **220** may be inserted, for example, an incision, a wound, a cut and/or optionally including a separate port device. "Tool channel" relates to a part of the workspace device (e.g., device **220**) through which a tool can be inserted into volume **234**.

At **426**, device **220** is deployed, e.g., made ready to receive tissue thereinto. It is noted that deployment may be delayed if workspace device **220** is not needed yet. Optionally, the orifice is oversized for the tissue to be received. For example, if a tissue is to be received, that tissue, when best oriented, has a maximal cross-sectional area which is desirably smaller than the cross-sectional area of the orifice. This is termed the tissue "minimal" cross-sectional area and is the smallest "maximal" cross-sectional area thereof. Optionally, there is a factor of at least 1.1, 2, 2.5, 4 or intermediate or greater factors, to assist in insertion. Optionally or alternatively, to defining by area, the orifice has a shape which is larger by at least 10%, at least 20%, at least 50%, or intermediate or more in all directions than a geometric projection of the tissue for which it is intended on a plane.

FIG. **4**C is a detailed flowchart of a method of deploying a workspace device during a laparoscopic procedure, in accordance with some exemplary embodiments of the invention;

After insertion into the body (FIG. **5**), the device is optionally rigidified, for example, by insertion of one or more rigid elements thereinto or by inflation thereof. Rigidization can also be carried out later in deployment. In some embodiments of the invention, rigidization comprises inflating one or more inflatable chamber therein. In some embodiments of the invention, rigidization comprises releasing the device to self expand, for example, by retracting a sheath or an internal mandrel which holds the device in a closed condition. In some embodiments of the invention, rigidization comprises interlocking one or more rigid components. It is noted that in some embodiments the device already includes one or more rigid elements, but the device is not in a rigid deployed configuration. Expanding the device can accomplish this, for example, using one of the methods described herein. Rigidity of the device is optionally provided by a mechanical interaction between tensile properties of the thin membrane (**232**) and the rigidity of one or more rigid elements. The rigid elements are also termed herein "rigid struts".

In a particular embodiment of the invention, the rigid struts are formed of plastic and are pre-deformed to expand device **220** by bending and stretching a thin membrane therebetween. In some embodiments of the invention, pre-deformation is provided using a spring or by positioning magnets with like poles that repel each other, the repelling occurring when a limiting force (e.g., a sheath) is removed.

In another particular embodiment of the invention, wall **232** is doubled layer (e.g., see FIGS. **8**D-E below) and includes one or more inflatable chambers defined between the walls, so that inflation thereof causes the chambers to act as rigid struts.

In some embodiments of the invention, insertion and inflation are by a single step. For example, delivery system **502** may use air (or liquid) pressure to both advance device **220** and inflate it.

In another embodiment, the rigid elements extend out of the body and can each pivot about a point near or at opening **128** (e.g., may lie in channels or be attached to device **220** at or about opening **128**). This allows the device to be laterally expanded by manipulating of the ends that are outside the body.

In some embodiments of the invention, deployment is by active mechanical manipulation, for example, (e.g., see FIGS. **22**A-**22**C) changing the relative position of two components of the device, for example, by rotation or a threaded element, insertion of an element or pulling of an element (e.g., a string **205** (FIG. **2**) attached to a far side of device **220** or rigidifying element thereof, optionally manually activated).

In some embodiments of the invention, deployment is by insertion of elements and/or in stages. For example, an elongated element may be inserted into workspace device **220** to axially deploy device **220** and an inflatable element may be inserted to volumetrically deploy device **220** (or the same deployment element may be inflated or expanded). Optionally, the rigid struts of device **220** in such an embodiment are plastically deformable to maintain the shape after such inflation, or may mechanically interlock to maintain the shape.

At **454** device **220** is deployed directionally, such that orifice **230** is pointed in a direction from which tissue is to be provided into orifice **230**. Optionally, the device is inserted in a directional manner. For example, a directional indicator, for example, **43**, **43***a* (FIG. **11**), may be used, which is visible outside the body. Optionally or additionally, frame **242** is rotated, rotating device **220** with it. Optionally, this is done under visualization, for example, using a previously intra-abdominally inserted imager. It is noted that some embodiments feature a workspace device which is thin walled and not amenable to manipulation. Optionally, this is avoided or reduced by inserting in a correct direction (e.g., and using a device with a laterally directed orifice **230**) and/or by manipulating frame **242**, rather than wall **232**. Optionally, one or more gripping points **231**, including stronger and/or stiffer material, are provided on wall **232**, to enable gripping of those points and manipulating wall **232** thereby, without damaging the integrity of wall **232**.

A potential advantage of some embodiments of the invention is prevention of damage to intra-abdominal organs during insertion and deployment. Optionally, this is facilitated by correct selection of device **200** and by insertion of rigid elements and/or expansion only after correct placement relative to intra-abdominal organs is noted.

At **456**, device **220** is optionally deployed axially. In some embodiments of the invention, the size of volume **234** is determined, at least in part, by axial advance of wall **232**

relative to frame **242** and/or opening **128**. Optionally, advance is controlled by using an inner mandrel and/or by selecting rigidifying elements for insertion or inflation of a desired length and/or geometry (e.g., curvature).

At **458**, device **458** is optionally deployed volumetrically, e.g., expanded to define a desired size and shape of workspace volume **234**. Optionally, this is done by selective inflation or selective use of rigidifying elements. Optionally or additionally, this is done by selectively shortening one or more internal chords of device **220**, for example, by pulling on one or more tensile elements **205** which interconnect a rigidifying element **218** or **222** to tube **246** or frame **242**, thereby shortening the chord. Optionally, element **205** (for example a wire) includes one or more widened sections along its length which can lock into a notch formed in frame **242**. Other interlocking mechanism can be used as well. Optionally or alternatively, element **205** lies (and slides) within a rigidifying element. Optionally or alternatively, element **205** is used for changing the shape of device **220**, for example, after orifice closure. If multiple elements **205** are provided, then selective shortening of such elements can be used to provide asymmetric control of the shape of device **220**.

FIG. **10**D is a side view of a workspace device **1060** using tensile members **1066** optional within rigidifying members **1064** for controlling a geometry of a wall **1062** of device **1060**, in accordance with some exemplary embodiments of the invention. Optionally, a plurality of members **1066** extend out of the body and may be, for example, individually and/or manually shortened to control said geometry. Optionally, as shown, members **1066** do not extend to a bottom of device **1060**. Different members may extend different vertical amounts. Optionally, members **1066** are fixedly coupled to rigidifying members **1064** at ends of members **1066**. Optionally, a lock, not shown, is used for fixing the relative lengths of members **1066**. For example, a plurality of channels for members **1066** may be formed in a ring and a conical plug inserted into or retracted form the ring to lock the members in place. In another example, the members are attached to one or more rigid members which are lockable in place relative to a rigid portion of device **1060**, extending out of the body.

In some embodiments of the invention, the volume of device **220** is selected according to need and this may set the shape and/or location of the deployment. This type of selection can be useful for tissue which is separated, because it may be easier to move the tissue than find an alternative location for device **220**.

At **460**, the geometry of orifice **230** is optionally arranged, for example, its shape and/or size. In one example, a normally closed orifice is opened. In another example, lips **202** are manipulated to partially close the orifice and/or change its shape. In another example, lips **202** close (or open) by inflation, and partial inflation is applied to shape them. Optionally or alternatively, orifice **230** is normally open.

At **462**, correct placement of device **220** is optionally verified, for example, using an intra-abdominal imager and/or by imaging through device **220** from inside.

With regard to deployment it is noted that in some embodiments of the invention, contact with intra-abdominal tissue and organs is avoided. Optionally, deployment is manual, allowing potential such contact to be monitored during deployment. Optionally or additionally, some arts of deployment are automatic (self-deployment) and correct selection of device **220** may be used to avoid undesired contact. This may be in contrast to some existing retrieval bags, where the bag lies on intra-abdominal organs. In some embodiments of the invention, device **220** hangs from abdominal wall **124** and may be therefore suspended in space.

It is noted that contact, especially forceful contact, during usage are optionally avoided.

Referring back to FIG. **4**B.

At **428**, tissue to be process **508** is optionally inserted into workspace volume **234** via orifice **230**. In some embodiments of the invention, such insertion is by grapping tissue **508** and pushing it into volume **234**. Optionally, device **220** is stiff enough to avoid bending away if/when tissue **508** contacts wall **232** rather than pass smoothly through orifice **230**.

In some embodiments of the invention, a tissue engaging tool, such as a grasper is inserted through tube **246** and out of orifice **230** to grab the tissue and pull the tissue into orifice **230**.

In some embodiments of the invention, a grasper (e.g., laparoscopic inserted through a separate laparoscopic port and/or valved entry **248**) is used to hold lips **202** of orifice **230** steady during such manipulations.

At **430**, the correct placement of tissue **508** is optionally imaged, for example, using an intra-abdominal imager, and/or via an imager inserted through opening **128**. In embodiments where wall **232** is transparent or includes one or more transparent areas, imaging may be through wall **232**.

At **432** orifice **230** is closed and at **434**, the orifice is optionally sealed and/or otherwise isolated from the intra-abdominal cavity. It is noted that in some embodiments, closing and sealing are two different acts. Sealing may allow the creation of a negative pressure differential between workspace volume **234** and intra-abdominal cavity **122**.

As noted, in some embodiments of the invention orifice **230** is normally closed, so it can be released to close. In others, it may be normally open or neutral and be closed, optionally manually. It is noted that direct manual manipulation may not be easy. FIG. **18** shows an example of manual manipulation of a zipper **68** using a laparoscopic grasper **100**. FIG. **19** shows an example of manual manipulation of a zipper using a drawstring **70**. In some embodiments of the invention, such manipulations form outside the body are replaced by allowing a manipulation inside the body, for example, drawstring **70** or **204** may be used to activate a closing mechanism which brings lips **202** towards each other. In some embodiments of the invention, a grasper inserted through opening **248** or opening **244** is used to manipulate lips **202** to close orifice **230**.

FIG. **10**B shows an exemplary sliding closure.

In another example, deflation of inflatable chambers in lips **202** allows a pre-deformed element (or a magnetic seal) in lips **202** to assert itself, as it does not need to work against these chambers, and close orifice **230**.

An example of a normally closed orifice is a valve, for example a one way valve (e.g., formed and/or supported by lips **202**, for example, a flap valve or a duck valve or other type of vale optionally using flexible leaflets), which closes once all of tissue **508** passes therethrough. A tool may be needed to clean lips **202** so that they close against each other. In some embodiments, lips **202** seal to tissue (not tissue **508**) rather than to each other. For example, if a cyst is to be drained, tissue **508** (the cyst) may be brought into volume **234** and lips **202** closed on tissue attached to the cyst. The point of drainage of the cyst is thus isolated from abdominal cavity **122** and may be more safely drained, for example, by lancing and suction. In some embodiments of the invention, lips **202** include a plurality of apertures and are attached to

a source of suction (e.g., **204** being a tube connecting to suction source **210**), so that lips **202** can attach and seal to tissue using suction forces. Optionally or additionally, lips **202** include a soft layer to provide compliance to contacted tissue geometry. In some exemplary embodiments of the invention, suction apertures along one or more lips **202** are used to seal lips **202** to each other and/or other parts of wall **232**.

In some embodiments of the invention, orifice **230** is closed by covering with a flap, for example, folding a flap over the orifice. This is shown, for example, in FIG. **8**B.

In some embodiments of the invention, orifice **230** is closed by rolling up a sleeve, for example, as shown in FIG. **7**C.

In some embodiments of the invention, a purse-string suture is provided in lips **202** and pulling on drawstring **204** or releasing the suture (or other self-contracting element in lips **202**) to contract (if it is a self contracting suture) closes orifice **230**.

In some exemplary embodiments of the invention, closing is by advancing a suture over a drawstring to over an extension of the orifice lips (e.g., the sleeve).

In some embodiments of the invention, sealing (and optionally closing) includes applying adhesive or heating (e.g., using a grasper with a heating element) to weld together lips **202**. (e.g., FIG. **10**C).

In some embodiments of the invention, closing is by twisting lips **202**, for example, if they extend in the form of a sleeve. Optionally or additionally, such lips may be brought into an apertured closure element and held therein by friction, optionally due to radial contraction of the element. (e.g., FIG. **9**M)

In some embodiments of the invention, lips **202** overlap with each other in a circumferential direction, to provide closure. In one example, one of lips **202** is predisposed or otherwise has a stable state when it overlaps the other lip. For example, both the lips may be predisposed to extend convexly towards orifice **230**, rather than concavely when the orifice is open, as shown. In another example, the lips extend away from device **220** and overlap, meeting to provide closure. Optionally, a drawstring **204** is used to approximate lips **202** and/or release or expose adhesive thereat.

In some embodiments of the invention, closure and/or sealing is by bringing an extension of lips **202** outside of the body, for example, as shown in FIGS. **9**A-N.

It is a particular feature of some embodiments of the invention that closing orifice **230** does not require tissue **508** to be moved (e.g., more than 4, 3, 2, 1 cm in any direction or smaller or intermediate amounts). This is in contrast to bags where the edges of the opening used to insert the tissue are then pulled out of the body, where the tissue will be jostled and moved, possibly falling out of the bag.

At **436**, the quality of the sealing is optionally verified. In one example, verification is by filing workspace volume **234** with a fluid and seeing if any leaks into the abdominal cavity. In another example, verification is visual. In another example, de-pressuring workspace device **220** should cause some change in shape due to the larger intra-abdominal pressure and due to the flexibility of some parts of wall **232** (if any). This may be visually noted. Optionally or additionally, wall **232** includes a dedicated chamber or section which deforms due to the pressure difference, giving a visual indication that there is a seal. As an example, a small flexible wall section with a dome shape is expected to change its shape according to pressure differences thereon. Optionally, a tube extends from said dedicated chamber to outside the body to provide an indication of pressure, outside the body.

At **438** device **220** is already set up for resisting external forces, such as said pressure differential and/or contact by tools and/or tissue in the abdominal cavity. Such resistance is optionally ongoing to prevent leakage of contents of workspace volume **234** into intra-abdominal cavity **122**.

As noted above, in some embodiments of the invention intra-abdominal pressure is not reduced and device **220** may be suspended from abdominal wall **124** so as to avoid contacting intra abdominal organs or other tissue.

At **440** device **220** is already set up for resisting internal forces, such as may be applied by tools moving and/or operating in volume **234**. Such resistance is optionally ongoing to prevent leakage of contents of workspace volume **234** into intra-abdominal cavity **122**. In one example, vacuum is applied in volume **234**. However, as wall **234** includes rigidifying elements, this optionally does not cause collapse (e.g., reduction in volume by **205**, 30%, 40% or intermediate or greater amounts) and/or local collapse of wall **232**, thereby avoiding damage to tissue outside wall **232**.

At **442** workspace **220** is set up for tissue processing, for example, by changing a shape thereof, moving away from sensitive tissue (e.g., avoid keeping the aorta in a direct line of operation of tools) and/or changing orientation relative to gravity. Optionally, such changes are by manipulating frame **242** and/or pulling on wires **205** and/or inserting or removing rigidifiers and/or changing inflation pressures. In some exemplary embodiments of the invention, preparation comprises inserting a shield into volume **234**, for example, to prevent accidental damaging of the wall and/or opening of orifice **230** by contact with a tool and/or other tissue processing activities. For example, the shield may be a self-expanding disc mounted on an arm, and held in place so the disc is between a sharp tool and wall **232**.

At **444**, tissue **508** is optionally processed, for example, by providing tools thereinto. For example, a lance may be used to lance a cyst; a morcellator may be used to reduce tissue dimension; a grasper or other tissue manipulator may be used to manipulate tissue and/or hold it in place for other tools; a transfection tool may be used to genetically alter tissue; a medicament applicator (e.g., by spray, needle injection and/or spreading) may be used to apply a pharmaceutical to tissue; an implant delivery tool may be used to deliver an implant such as an anastomosis device or a clip; a suturing tool may be used to suture tissue; an electro-ablation or electro-cutting tool may be used to heat tissue; a welder maybe used to weld tissue and/or blood vessels in a tissue; a therapy tool may be introduced to apply therapy, such as light therapy, to tissue; a suction tool may be used to extract fluid and/or small particles, an ablator may be used to ablate tissue and/or a cutter may be used to cut part of tissue.

It is noted that because treatment is inside workspace device **220**, side effects, such as contaminating or inadvertently affecting other intra-abdominal tissue, may be reduced or avoided.

In some embodiments of the invention, the tool used is a morcellator, optionally a standard morcellator (e.g., which is sized to fit through tube **246**). Optionally, rigidified wall **232** allows the use of a wider range of morcellators without worrying about inadvertently damaging intra-abdominal tissues.

At **446**, access to intra-abdominal cavity is provided **122**. This may be useful if a tool is inserted into device **220** from cavity **122**. Optionally or additionally, this is used when

intentionally releasing treated tissue (e.g., a treated tissue graft) from volume **234** back into cavity **122**, for example, for implantation thereof. Optionally, such exchange is by reopening orifice **230** (e.g., deflating an inflatable orifice, unzipping a zipped orifice). Optionally, orifice **232** may be reclosed and/or resealed thereafter, one or more times.

At **448**, device **220** is removed and if inserted through a port, the port is optionally reusable. In some embodiments of the invention, device **448** is integral with a port (e.g., frame **242** forming part of the port or attached thereto). Optionally, neck **246** can be separated from frame **242** (and valve **244** is optionally directly mounted on frame **242**, as may be in other embodiments as well), leaving frame **242** to act as a laparoscopy port. Optionally, separation is by a tear string tearing a tear line in neck **246**, which tear line lies, for example, outside of the body.

In some embodiments of the invention, it is important to maintain device **220** in a sealed configuration during removal. Optionally, volume **234** is optionally emptied first, for example, by suction. Following that, the workspace volume **234** is optionally collapsed. FIG. **21** shows an example of reducing the dimension of workspace device **10** by removing a workspace expanding insert **50**.

In some embodiments of the invention, closure mechanism found in lips **202** is configured to not catch on frame **242** (if existing) and/or on intra-abdominal tissue and/or on a laparoscopy port during removal. Optionally, for example, if a zipper is used, the zipper or other sealing element seals when moved away from the abdominal wall, so if such catching occurs, it will not unseal device **220**.

Exemplary Materials and Other Properties of Workspace Device

In some embodiments of the invention, wall **232** is formed of a membrane, for example, formed of a polymer, for example, polyurethane or other hydrocarbon, or a silicon-based polymer, for example, between 10 and 1000 microns thick, for example, between 20 and 400, for example, between 50 and 100 microns thick. Optionally, the wall is composed of two or more layers of such thickness. While in some embodiments wall **232** is gas impermeable, in some embodiments, wall **232** is gas permeable, for example, being formed of a woven fabric or apertured sheet. This may allow a less stiff and/or strong structure to be used, as resistance to intra-abdominal pressure differential will not be needed. Optionally, the wall is impermeable to cells, for example, passing only material smaller than 10 microns, 5 microns, 1 microns, 0.5 microns, 0.01 microns or intermediate or smaller, in their smallest dimension.

In some embodiments of the invention, device **220** includes one or more rigidifying elements (e.g., **218**, **222**). Optionally, they are all formed of a same material. Alternative, different ones are of different materials. In some embodiments of the invention, the material is shape memory and/or super elastic, for example, being formed of nitinol or a suitable polymer, for example, a silicon or hydrocarbon polymer. Optionally or additionally, the material is metal, for example stainless steel. In some exemplary embodiments of the invention, an element has a maximal cross-sectional diameter over most of its length of between 0.1 and 4 mm, for example, between 0.3 and 2 mm, for example, between 0.5 and 1.2 mm.

In some embodiments of the invention, channels in or on wall **232** are welded on patches or welds between two layers of wall **232**. Optionally or additionally, such channels are formed by attaching a ready-made channel (or chamber) to wall **232**. In some embodiments of the invention, rigidifying elements are embedded in wall **232**. Optionally or additionally, at least one such element is adhered to the inside, outside and/or between layers of, wall **232**.

In some embodiments of the invention, the rigidifying elements are elastic, in that if deformed, they return to a desired resting state. This may assist in resisting the effect of momentary high forces, such as due to inadvertent tool contact with wall **232**. It is noted that in other embodiments, workspace device **220** is plastically deformed, for example, using plastically deforming rigidifying elements. In some embodiments of the invention, this means that the elements can be plastically deformed without requiring a degree of deformation which would tear wall **232**.

It is noted that the term "rigid" as used herein is relative and relates to the ability of the device and/or element to withstand deformation by expected forces after deployment, for example, due to pressure differentials, manipulation of tissue inside device **220** and/or contact with tools and/or abdominal tissue. For example, a thin nitinol wire may be sufficient to maintain the shape of device **220**, but might be bendable by hand. Optionally, device **220** can resist collapse under a pressure difference of 15, 20, 25 or intermediate or greater pressures mmHg.

In some embodiments of the invention, while rigid, device **220** avoids parts with a high curvature, such as finger-like projections, which could apply undesired trauma to intra-abdominal tissue. For example, no intra-abdominal part with a radius of curvature smaller than 10 mm extends more than 4 mm from a general surface of device **220**, unless it is soft enough to not cause trauma. In some embodiments, this property is true also during insertion (e.g., according to FIG. **5** example, where insertion is of a soft leading part, optionally using air pressure).

In some exemplary embodiments of the invention, the cross-section of the orifice is circular, ellipsoid and/or rectangular. In some exemplary embodiments of the invention, the cross-section of the device is circular, ellipsoid and/or rectangular. Other cross-sectional shaped may be used, for example, to fit a tissue and/or operation location. Furthermore, the device may have a non-uniform cross-section.

In some embodiments of the invention, the shape of device **220** is generally egg shaped, with the narrow dimension horizontal. Other shapes may be provided as well, for example, spherical, horn shaped and tubular. Optionally, the length of the device is between 0.75 and 3 times the maximum width of the device. In some exemplary embodiments of the invention, orifice diameter is between 10 and 110 mm, for example, between 20 and 70 mm, for example, between 30 and 50 mm or intermediate sizes. In some exemplary embodiments of the invention, optionally, device **220** is rotationally symmetric around a long axis thereof. In some embodiments, the axis bends, for example, in a horn-shaped device. A potential advantage of such shape is that even though insertion is at an umbilical area (or other convenient location), the tissue can be placed where convenient (e.g., side opening) and/or processed at a place and direction so the aorta is not along a direct line connecting opening **128** and the tissue. In some embodiments of the invention, other shapes are used, for example, to better match the shape of the expected available volume in intra-abdominal cavity **122**. It is noted that the location of orifice **232** may also be selected according to need and be, for example, at a lateral side or at a distal side of device **220**. Optionally, orifice **232** is round or ellipsoid, though other shapes may be provided as well. In some embodiments of the invention, orifice **232** extends between 20% and 80% of a projected length of the wall of device **220** on which it is

found, such that there is wall material surrounding the orifice, for example, to an extent of between 10% and 30% of a diameter of the orifice.

In some embodiments of the invention, the intra-abdominal portion of device **220** is between 10 and 200 mm in length, for example, between 30 and 150 mm in length, for example, between 40 and 110 mm in length.

In some embodiments of the invention, device **220**, when deployed, is between 10 and 200 mm in width, for example, between 30 and 150 mm in width, for example, between 40 and 110 mm in width.

In some embodiments of the invention, frame **242** is between 2 and 20 mm in outer diameter where entering abdominal wall **124**, for example, between 3 and 15 mm. Optionally, the inner diameter (e.g., of tube **246**) is between 0.5 and 3 mm smaller than the outer diameter. In some embodiments of the invention, when not deployed device **220** (other than any part intended to not pass through abdominal wall **124** is between 1 and 30 mm in maximal cross-sectional extent, for example, between 2 and 20 mm, for example, between 4 and 15 mm.

In some embodiments of the invention, when deployed, the width of device **220** expands by a factor of between 1.1 and 40, for example, between 3 and 20, for example, between 5 and 10. Optionally, the expending part extends past any outside rigid portions such as frame **242**.

In some embodiments of the invention, the volume of volume **234** is between 10 and 2000 cc, for example, between 50 and 1500 cc, for example, between 500 or 700 and 1000 cc.

For applications other than the abdominal cavity, other sized may be used, for example, insertion diameter of between 1 and 10 or 20 mm, and/or bag volume of between 1 and 100 cc.

Exemplary Use of Negative Pressure Difference

FIG. **6** is a schematic showing of the effect of negative pressure difference, on leakage, in accordance with some exemplary embodiments of the invention. In some embodiments of the invention, a pressure differential is maintained across wall **232** between intra-abdominal cavity **122** and workspace volume **234**. In some embodiments of the invention, this is used to prevent or reduce leakage of material from volume **234** to cavity **122**, due, for example, to damage or imperfect manufacture or sealing.

FIG. **6** shows an example where a tear **602** is formed in wall **232** (but it could also be an imperfect seal at orifice **230**). Due to the pressure differences, fluid will tend to flow according to arrows **604** from intra-abdominal cavity **122** into workspace volume **234**, and tissue **508** (shows as a sliver through opening **230** left a little open for exposition purposes) inside workspace volume **234** will not leak out. Excess pressure may bleed out of opening **126** to the operating room, if opening **126** is not sealed. Optionally, device **220** includes a sealed chamber at atmospheric (or other pressure lower than intra-abdominal pressure), which chamber can provides compliance, by collapsing if there is inflow through tear **602**. Optionally, such a chamber (e.g., in the form of chamber **228**) is vented to outside the body.

In some embodiments, no pressure differential is provided, rather a pressure equilibrium is provided. This will still avoid tissue flow out of volume **234** which would otherwise be due to excess pressure inside volume **234**.

In some embodiments, volume **234** does have a higher pressure than cavity **122** and the above described mechanism is not available. Optionally, a valve **233** (FIG. **2**) is provided to allow pressure differences to bleed through, so as to equalize pressure inside and outside of workspace device **220**, without allowing passage of tissue therethrough. Optionally, valve **233** includes a filter (e.g., of tight mesh) to block cellular matter.

In some exemplary embodiments of the invention, volume **234** is inflated to have a pressure above ambient, but below intra-abdominal levels.

Exemplary Safety Features

Referring back to FIG. **2**, device **200** can include one or more safety features, for example:

(a) a protective mesh **224**, optionally spaced form wall **232** or a thickening **206** of wall **232** opposite opening **226** and/or at other locations where axial advance or other strong motions of an inserted tool are expected, for example, opposite orifice **232**;

(b) rigidity defining a concave shape at a top side of device **220** and/or at other parts of wall **232**, to prevent suction of wall **232** into a morcellizer tool;

(c) small enough distance between rigid elements to prevent parts of wall **232** from fitting into a tool such as a morcellizer and reaching a blade thereof;

(d) ongoing removal of blood, smoke and/or other debris from volume **234**, for example, using suction **208**, optionally from a bottom (gravitational) of volume **234**;

(e) blood or tissue congealing and/or absorbing material **226**, to reduce the amount of fluid present to leak out;

(f) the above negative pressure differential to prevent leakage;

(g) suspension of device **220** without leaning against intra-abdominal organs, optionally at a distance of, for example, 1 cm, 2 cm, 3 cm or more or intermediate distances from such organs or tissue;

(h) insertion to a direction (e.g., not of bladder, aorta, GI tract) and depth where there is no tissue to be damaged, which is made possible, in part, due to the maintaining of insufflation of the abdominal cavity during insertion and later manipulation of some embodiments of device **220**.

(i) avoidance of sharp and/or hard edges, in some embodiments of the invention, to avoid tissue trauma;

(j) double layer walls (e.g., **206** and/or elsewhere), optionally filled with sponge or air, to avoid passing of forces across wall **232**;

(k) optional provision of suction between walls to extract debris, at a breech if one of the walls is breached;

(l) a valve **244** on opening **226** to prevent uncontrolled exposure of the surrounding environment (and physician) to debris; and/or

(m) providing a sensor **212** and/or **214** to detect pressure changes in volume **234** and/or strain on or treating of wall **232** and/or proximity of tools (or organs) thereto.

Exemplary Rib Arrangement

In some embodiments of the invention, device **220** has the form of metal ribs with a thin membrane stretched thereon. FIGS. **7**A and **7**B show one example of such a design, in accordance with an exemplary embodiment of the invention. As shown, a device **700** includes a plurality of vertical ribs **702** which are optionally connected at a distal end of device **700**, for example, at a cap **704** and/or optionally connected at a proximal side, for example at a ring **706** defining an aperture **708**. The ribs may instead be continuous. It should be noted that ribs can optionally move towards each other and apart in a circumferential direction. Reference **703** indicates two ribs which are optionally spaced apart to define an orifice therebetween. Optionally, the ribs can move towards each other to close a gap therebetween. In some embodiments, the closure is by a membrane which selec-

tively extends between ribs **703**, for example, as described in FIG. **7**C and/or in FIG. **9**, or by ribs **703** moving enough to approximate each other.

FIG. **7**B is a cross-sectional view of device **700**, also showing a membrane **710** mounted on the ribs. Membrane **710** is shown concave, due to the pressure difference between intra-abdominal cavity **122** and the inside of device **700**.

A reference **712** indicates an optional location for an orifice. Optionally, this location is a part of membrane **710** that is missing (e.g., a whole segment or part of one). The orifice is optionally closed by bring its two bordering ribs towards each other. Other rib arrangements are possible, for example, ribs that also bend in a circumferential direction, for example, s-shaped ribs. Optionally or additionally, one or more helical ribs are provided.

Exemplary Roll-Up Device

FIG. **7**C shows a device **720**, possibly using the design of FIGS. **7**A and **7**B, in which a membrane **723** is deployed after tissue insertion. In device **720**, a frame of ribs **722** is inserted into abdominal cavity **122**, exposed at least in part. This means that any space between two ribs can serve as an orifice to provide tissue **508** into device **720**. In the embodiment shown, the membrane is rolled up (**724**) at a bottom of device **720**, such that when unrolled up, it will: (1) cover ribs **722**; (2) separate tissue **508** from intra-abdominal cavity **122**; an d(3), unrolled all the way past abdominal wall **124** or if sealed to a surface inside the abdominal cavity **122**, for example at a top part of device **720**, will provide sealing.

In some embodiments of the invention, unrolling uses one or more pullers **726**, which act as tensile elements, such as straps or wires which are optionally rolled up with membrane **724**, such that retraction thereof causes unrolling and vertical movement of rolled up membrane **724**. Rather than rolling up, membrane **723** may be collected at **724** in other ways, for example, pleated.

A potential advantage of this design is ease of deployment, as there is no need to orient orifice **230**. Another potential advantage is that membrane **724** can be inserted ahead of ribs **722**, potentially reducing a cross-sectional diameter needed during insertion.

In some embodiments of the invention, device **720** comprises a frame which is then used with an existing retrieval bag (e.g., flexible membrane with one aperture formed in it), which is engaged by pullers **724**. It should be noted that pullers **726** can be used to hold even a standard bag against a frame **722**, possibly obviating the need to attach membrane **724** to a bottom of frame **722**.

In some embodiments of the invention, frame **722** is open at a bottom thereof. Optionally, in use, membrane **724** is placed in the body and spread out (optionally using a self expanding ring attached thereto and with a diameter optionally similar to that of frame **722**, or manually). Tissue **708** is then placed thereon. Then frame **722** is inserted into the abode and placed above tissue **508** and membrane **724**. Pullers **726** are used to pull membrane **724** up and towards frame **722**. Once membrane **724** pushes against frame **722**, the situation shown in the FIG. **7**C is achieved and pulling back further on **726** causes sealing of device **720**.

In some exemplary embodiments of the invention, the top of frame **722** includes a mesh or other space filling elements to reduce a distance between elements which support membrane **724** thereat. This may be useful if membrane **724** is more flaccid and therefore more liable to penetrate deeper into the inside of device **720**, between ribs of frame **722**, potentially getting caught in a morcelator or other tool.

Exemplary Single Opening Device

FIGS. **7**D and **7**E are side cross-sectional views of a workspace device **740** with permanent rigidifying elements **750** and a movable membrane **746** with a movable orifice **744**, in accordance with some exemplary embodiments of the invention; Device **720** is an example of a device with a single opening (in the membrane).

In a variation thereof, rather than membrane **724** being rolled up at a top thereof, a movable membrane **746** is provided with a collected section **748** that is, for example, rolled up or folded or otherwise collected at a lower portion thereof. In one example embodiment, membrane **746** has an orifice **744** for tissue ingress above the rolled up section thereof. FIG. **7**E shows that after tissue (not shown) is brought into device **740**, membrane **746** may be retracted out of the body, for example, using a tool **742**. Optionally, membrane **746** is pulled up far enough that orifice **744** is now outside the body. This may require that the length of membrane **746** below orifice **744** is greater than the height of device **740** as a whole. This design can also be used if there is only the single opening shown in FIG. **7**C (e.g., no separate orifice **744**), except that membrane **724** is pulled up rather than unrolled.

Optionally, membrane **724** (or **746**) is elastic so it can conform to frame **722** (or **750**), whose cross-sectional diameter may change at different portions along device **720**.

Exemplary Inflatable Device

FIGS. **8**A and **8**B are schematic showings (cross-sectional and perspective) of an inflation based workspace device **800**, in accordance with some exemplary embodiments of the invention.

In some embodiments of the invention, rigidifying is provided by inflation in addition to or instead of using naturally rigid elements. Device **800** has a double layer wall **804** which can be inflated (e.g., using saline or air, for example, using a syringe or a pump, not shown) to become taut and set the shape of device **800**. A cross-abdominal wall section **802** fits in opening **128**. Optionally, an orifice **808** for tissue ingress is provided below wall **804**.

A flap **806** is optionally folded over orifice **808** to close it and/or seal it. Optionally, an end **810** or an extension thereof of flap **806** is pulled towards opening **128** and/or out of the body. This type of orifice closure may be used with non-inflating embodiments as well.

In some embodiments of the invention, the use of an inflatable wall allows a distance to be maintained between tools in device **800** and intra-abdominal walls, which may allow deflation of the intra-abdominal cavity before processing of tissue **508** in device **800**. Optionally, such an inflatable chamber is provided with other designs of bags, for example, as known in the art where the same orifice is used for receiving tissue **508** and for receiving a morcellator.

In some embodiments of the invention, inflation is provided using a syringe coupled to wall **804** via a small diameter tube. Optionally, the tube is formed in neck **802**.

A potential advantage of using a single circumferential chamber is that there is no inward sagging between rigid segments. In other embodiments, sagging is controlled by including both axial and circumferential rigidifying elements.

While the figure shows a single circumferential inflation chamber, other designs may be used. For example, FIG. **8**C shows a device **820** having separate vertical inflatable segments **822** optionally separated by spaces **824** and **826** (which are optionally bridged by a thin membrane, not shown). Reference **828** indicates a hollow region within wall **822**. Optionally, an orifice is formed between two segments

822, for example, at 826. When both such segments are inflated, the opening at 826 closes. Alternatively an orifice 827 at a bottom of the device is provided (here shown closed by a flap, which flap is optionally drawable towards opening 128 by a puller 825. Reference 829 indicates the opening which crosses the abdominal wall, for example, for insertion of a morcellator therethrough.

FIG. 8D shows a device 840, where inner volume 234 is surrounded by a wall with a plurality of circumferential segments/chambers 846, located between and optionally formed from two wall surfaces 848 and 850. An orifice 844 for tissue ingress is optionally at a bottom of device 840 and an aperture for a morcellator and for crossing the abdominal wall is provided at 842. One or more air channels (not shown) may be provided at the walls surrounding 842 for conveying air or other fluid to chambers 846. Various mechanisms, for example, as describe herein may be used for closing orifice 874.

In alternative designs both one or more vertical and one or more circumferential segments are used and/or others shapes of segments, such as helical and/or diagonal, maybe provided. In some embodiments of the invention, the size and/or shape of the device can be set based on which segments are expanded. In some exemplary embodiments of the invention, inflating only some of the chambers (e.g., if there are 2, 3, 4, 5, 8 or intermediate or greater numbers of chambers) of device 840 can be used to set a shape and/or size thereof.

It is noted that failure of a single segment 846 or 822 need not cause a catastrophic failure of the device, though it may allow some leakage.

In some embodiments of the invention, inflation is used for device deployment. For example, for device 820, inflation of a single vertical segment may provide the device with axial rigidity so it is easier to push into the body. In device 840, inflation of a circumferential chamber can encourage a device to extend away from an insertion hole without immediately volume filling.

One consideration of some embodiments of the invention is avoiding tissue damage if the outer wall of device 800 breeches and high pressure fluid or air hits intra-abdominal organs. In some embodiments of the invention, the inflatable chambers include a foam, which slows down such flow. Optionally or additionally, a low enough pressure is sued. Optionally, a liquid is used, as then lower pressures may be suitable due to the incompressibility of liquid.

FIG. 8E is a cross-sectional view of an inflatable workspace device 860 showing various optional features, in accordance with some embodiments of the invention. A first optional feature is the provision of one or more inflatable chambers 866 near an orifice 867 thereof. Inflation of chambers 866 may be used to close and/or seal orifice 867. A second optional feature is the provision of multiple contiguous chambers 862, 764, (e.g., no membrane) which may not share a same inflation port and/or valve.

A third optional feature is a breech indicator 870, configured to lie outside the body. In an exemplary use, pressure in chambers 862, 864 is different (typically higher) from the ambient pressure within device 860 and/or pressure in the abdominal cavity. If a tool, for example, a morcellator damages an inside wall of device 860, this will cause a reduction in pressure and thereby collapse or other change in indicator 870. Damage to the outer wall, can also be expected to generate such an indication. In some exemplary embodiments of the invention, damage to a wall will cause blood to enter indicator 870.

It is noted that this type of indicator can be used also if device 860 is a non-rigidified specimen retrieval bag and indicator 870 is open to a volume of the bag. As long as such bag is inflated, indicator 870 will show one indication. Damage to the bag wall, will cause deflation and indication 870 can show it.

It is noted that an inflatable rigidifier can also be used with a one one-hole bag. For example, the bag being inserted into the abdominal cavity as in the art. after the tissue is placed in the bag through the one opening, the edges of the opening are retracted out of the body and the bag is rigidified by inflation.

Exemplary Sleeve Devices

FIG. 9A is a schematic showing of a workspace device 900 with a sleeve 906 extendible out of the body, in accordance with some exemplary embodiments of the invention.

Device 900 has a body 902 with an orifice 904 at a bottom thereof, with sleeve 806 extension from orifice 904 alongside body 902 to outside of the body. Also shown is a morcellator 110 processing tissue 508. Optionally, a puller 912, for example, a string, wire, cable, strap or other elongate flexible tensile member can be used to pull sleeve 906 out of the body. Optionally, suction 910 is provided to an end 908 of sleeve 910, for example, to remove blood from body 902.

In some exemplary embodiments of the invention, (e.g., FIGS. 8A, 8B), sleeve 906 does not exit the body, but it still isolates tissue 508 due to a fold formed therein by the extension and retraction thereof.

FIGS. 9B-9F are a series showing a workspace device 920 with an internal sleeve extendible out of the body, at various stages of use, in accordance with some exemplary embodiments of the invention.

At FIG. 9B, a tissue receiving orifice 922 is defined at a bottom thereof and a grasper 923 is optionally passed through device 920 to pull tissue 508 into device 920.

At FIG. 9C, orifice 922 is closed, for example, by advancing or bending a frame of device 920 or by pulling on a puller 926 which closes orifice 924 to an end 924. It is noted that while the frame is meant to provide rigidity, it can still be bent by suitable forces.

At FIGS. 9D, 9E, puller 926 is retracted, moving end 924 in a direction of the abdominal wall.

At FIG. 9F, puller 926 is retracted enough to bring end 924 outside of the abdominal cavity, thereby effectively sealing orifice 922.

FIG. 9G is a side view of a workspace device 930 with a lateral orifice 932 having extendible lips 934, in accordance with some exemplary embodiments of the invention. FIG. 9G shows one way of collecting the sleeve that may, after tissue 508 is moved into device 920, be extended to outside of the body using a puller 936.

Also shown in FIG. 9G is a feature usable with other embodiments, of one or more light sources 931, which may be mounted on, for example, wires 933 or be exposed ends of optical fibers, and provide light inside device 930. Optionally, sources 931 are passed into chamber 228 and/or other channels predefined in or on the wall of device 930.

FIGS. 9H and 9I are views of a curved workspace device 940 with a lateral orifice 946 having extendible lips 944, in accordance with some exemplary embodiments of the invention.

FIG. 9H is a perspective view and FIG. 9I is a cross-sectional view. The shape of device 940 is optionally chosen for one or both of two reasons. First, to allow the orifice to be closer to where the tissue to be processed originates.

Second, so that when processed, the morcellator is inserted at an angle, reducing the chance of damaging the aorta, which is under the umbilical region.

Lips **944** are shown to be a sleeve pleated around orifice **946**. Device **940** is also shown as being an inflatable device, with chambers **954** and optional non-inflatable sections **942** setting a shape thereof. A puller **948** is shown as extending **950** through a channel **952** to engage pleated section **944**. As noted herein, collection methods other than pleating can be used for sleeve **944**.

Optionally, not shown, a restrictor such as adhesive or a tearable suture are provided to maintain sleeve **944** in the collected configuration thereof. Optionally, the restrictor is selectively applied so as to set which parts of sleeve **944** will open first.

FIG. **9**J shows device **940**, if puller **948** and extension **950** thereof is attached as a purse-string **945** to sleeve **944**. Pulling on puller **948** will close orifice **469**. Optionally, this is a first step in pulling sleeve **944** out of the body. For clarity, channel **952** is not shown.

FIG. **9**K shows curved workspace device **940** with an extended lip **952** of orifice **944** collapsed radially and passing through channel **952** on the inside of the body in accordance with some exemplary embodiments of the invention.

FIG. **9**L shows a curved workspace device **960** with an extended lip/sleeve **964** of an orifice **966** configured for passing through a closure channel **972** on an outside of device **960**, when pulled by a puller **970**, in accordance with some exemplary embodiments of the invention. An optional feature is a strengthening **974** at an entrance to channel **972** (which may also be provided in other embodiments herein), to guide the collapse of sleeve **964** and/or prevent tearing of channel **972** by resistance thereof.

FIG. **9**M shows a workspace device **980** with an extended lip **988** of an orifice in a membrane **982** configured for passing through a restrictor **986**, for closure of the orifice, in accordance with some exemplary embodiments of the invention. Optionally, puller **984** is coupled to a part **990** of lip **988** and guides part **990** through restrictor **986**, pulling more of lip **988** along with it to close and seal the orifice.

FIG. **9**N shows a workspace device **992** with an extended lip **996** of an orifice **994** configured for being pulled outside the device and out of the body, by a puller **948**, for closure of the orifice, in accordance with some exemplary embodiments of the invention.

Exemplary Side Access Device

FIG. **10**A is a schematic showing of a workspace device **1000** where access to a morcellizer **110** or other tube is via an opening between the workspace device and the abdominal cavity, in accordance with some exemplary embodiments of the invention.

As shown, morcellizer **110** accesses tissue **508** via a first orifice, optionally including a valve for sealing, in device **1000**, separate from an orifice **230** for tissue ingress. In some embodiments of the invention, the openings and orifice are opposite each other, for example, substantially diametrically opposite each other, or at least 90 or 120 degrees apart around the circumference of device **1000**.

As can be seen, device **1000** does not cross the abdominal wall and is wholly within the abdominal cavity. For example, an inserter **1014** is used to insert device **1000** past opening **128** in the abdominal wall. A safety cable **1012**, for example, a wire or a strap is optionally provided to assist in removing device **1000** and/or maintain it suspended in space and/or otherwise apply a positioning force to it. It is noted that such a safety cable may be provided with any of the other embodiments described herein.

Exemplary Reduced Curvature Orifice

It is noted that closing and/or sealing a curved orifice, especially with curvature in two dimensions may be difficult. In some exemplary embodiments of the invention, the orifice is designed so there is only one dimension of curvature. Optionally, such design may also prevent catching of the closure mechanism on tissue or tools, when the workspace device is retracted from the body.

FIG. **10**B shows a workspace device **1020** with a sliding closure **1030**, in accordance with some exemplary embodiments of the invention. It is noted that the sliding closure is just one way of closing a linear orifice. Others, for example, being described in this document.

As shown, an orifice **1026** has two lips **1028** which lie in a same plane, and when closed, optionally lie along a straight line. This may be achieved, for example, by lips **1028** being stiff and/or by suitable geometries for a membrane **1022** and one or more stiffener ribs **1024**. Lips **1028** are optionally elastically predisposed to be normally open.

Reference **1034** indicates a device neck for a morcellator entrance. Slider **1030**, which optionally slides into the body along a rail (not shown) on neck **1034** is a slotted elongated beam, optionally a slotted two, which pinches lips **1028** within its slot.

FIG. **10**C is a detail view of an adhesive sealing mechanism, in accordance with some exemplary embodiments of the invention. This mechanism may be used with closure **1030**, or with a zipper like device as shown in FIG. **11** below or also for curved lips of an orifice.

A first lip **1040** and a second lip **1042** are attached by an adhesive layer **1052** (on one or both lips). This layer is optionally exposed when protective covers **1050** are removed therefrom. Optionally, a single mechanism is used to approximate, expose and attach the two lips. In one example, a peeler **1048**, for example, a roller or a wedge, removes protective layer(s) **1050**. A pair of rollers or other sliding elements **1046** press together parts of lips **1040** and **1042** which feed into the mechanism. Optionally, a puller **1044** is provided for moving the mechanism.

Exemplary Workspace Device with Zipper-Like Mechanism

Turning now to an exemplary embodiment of the device and with initial reference to FIGS. **11-18**, the specimen retrieval (removal) device is designated generally by reference numeral **10** and includes a proximal portion **12** and a distal portion **14**. As used herein, proximal refers to the portion or region closer to the user and distal refers to the portion or region further from the user. The device **10** has a tube (tubular portion) **11** made of an elastic material and has an outer wall **16**, an inner wall **18** and a plurality of longitudinal slits **20***a*, **20***b*, **20***c*, and **20***d* which are formed through the full thickness of the wall to thereby form four separable arms or leaves **22**, **24**, **26**, **28**. In the illustrated embodiment, the four slits **20***a*-**20***d* are equidistantly spaced, although varied spacing is also contemplated. Note that although four slits are shown, it is contemplated that a fewer number of slits or a greater number of slits can be provided to form a different number of arms (leaves) with the number of arms corresponding to the number of slits. The number of slits/arms will affect the shape of the device. The slits **20***a*-**20***d* enable the leaves **22**-**28** to move from a non-spread (collapsed) insertion position to a spread or expanded position forming arch-shaped leaves. This is achieved by an expander member **50** discussed in detail below. The slits **20***a*-**20***d* do not extend the full length of the tube **11** so the

leaves **22-28** remain attached at a proximal end and at a distal end. The tube **11** has an opening at a proximal end and a cap **44** closes off the distal end. The cap **44** can be a separate component or integrally (monolithically) formed with the tube **11**. The cap can be dome shaped or other shapes.

Attached to an internal surface of each of the leaves **22-28** is a projection or knob, also referred to herein as a rigidifying or reinforcing member, which can be made of a plastic material. More specifically, projection **32** is attached to the internal surface of leaf **22**, projection **34** is attached to the internal surface of leaf **24**, projection **36** is attached to the internal surface of leaf **26** and projection **38** is attached to the internal surface leaf **28**. The projections **32-38** are preferably positioned only in a proximal region of the leaves **22-28**, i.e., at the base portion of the leaves, as shown. The projections are preferably composed of a material having a rigidity greater than the rigidity of the tube **11** to maintain it in an expanded position. The proximal edges of projections **32**, **34**, **36**, **38** have a proximal engaging or abutment surface (see e.g., surfaces **32***a*, **36***a* of FIGS. **12**A and **2**B) to receive the engaging member (expander) **50** which applies a radial force on the projections **32-38** to force them radially outwardly to expand the leaves **21** of tube **11** radially outwardly. In the illustrated embodiment, the projections **32-38** can have a wedge shape so that the outer wall angles inwardly in a distal direction. Stated another way, the projections **32-38** each taper in a distal direction so that the proximal region has a larger cross-sectional dimension than the distal region. This provides a larger engaging surface for the engaging member (expander) **50**. However, it should be appreciated that other shaped projections are also contemplated to perform the function of expanding the tube **11** in response to engagement by the expander **50**. It is noted that in some embodiments a rigidifying member includes also the leaf (arm).

The expander **50** optionally has a flange **52** to restrict axial movement of the expander **50** within tube **11**, i.e., prevent the expander **50** from slipping into the tube **1**. Expander **54** also has a slit valve **54**. Tubular portion **56** extending distally from flange **52** slides through tubular portion **49** of mounting tube **48**, and beyond its distal end so edge **56***a* can engage projections **32-38**.

The tube **11** is movable (expandable) by the expander **50** from the collapsed position of FIGS. **12**A, **13** and **14** to the expanded position of FIGS. **12**B and **15**. In the expanded position, the device **10**, i.e., the tube **11**, forms a box-like structure in the shape somewhat resembling a football with each of the leaves **22-28** forming an arch shape as its distal edges are connected, although other expanded shapes are also contemplated. As shown in FIG. **12**A, the tube **11** in its collapsed position has an internal diameter (transverse dimension) designated by D**1** which is substantially constant along a length of the tube **11**. In the expanded position, the device **10**, i.e. tube **11**, has a larger internal diameter (transverse dimension), with D**2** designating the largest diameter (transverse dimension) region.

The tube **11** can be made of transparent material to enable viewing inside the tube **11** by a laparoscope positioned in the body cavity adjacent to and outside the tube **11**. The laparoscope can be inserted through another trocar port or body opening. Alternatively, the tube **11** can be composed of non-transparent material while the covering of the leaves (discussed below) and spaces between the leaves is composed of transparent material so visualization can occur between the leaves **22-28**.

A material **60** covers the leaves, i.e., spans the space between the leaves **21** to form an enclosed internal space within the tube **11**, designated by reference numeral **27** in FIG. **12**B. In other words, the cover (or sheet(s)) creates the four walls (sides) of the device, e.g., of the somewhat football shape. The sheets or covers can be made of a transparent plastic material. A single material can be placed over the leaves **22-28** or alternatively separate sheets or covers of covering material can be placed to span adjacent leaves. In either case, an enclosed space is formed except for longitudinally extending side opening **62** between two adjacent leaves (see FIG. **5**). In the illustrated embodiment, the opening **62** is shown between leaves **26** and **28** by way of example and is defined between edges **64**, **66** of covering **60**. The opening **62** will preferably be kept by the clinician facing the patient's anterior abdominal wall. A locking or sealing mechanism can be provided to close the opening **62**. In one embodiment, shown in FIGS. **16** and **17**, the locking (sealing) mechanism includes a zip-lock mechanism **68** which is slid proximally (or alternatively distally) to close the opening **62** by bringing edges **64** and **66** together. This fully encloses the specimen within the device **10** to block leakage of fluid. A double layer of zip-lock mechanisms can also be provided. In some exemplary embodiments of the invention, the zip-lock mechanism is a mechanism which brings together and interlocks two lips which have a spatially interfering design and/or which include adhesive.

Optionally, zip lock mechanism **68** is provided after deployment, from outside the body, for example, using a grasper **100**. Optionally, for example, if the mechanism of FIG. **10**D is used, zip-lock mechanism **68** may be removed after edges **64** and **66** are brought together.

Exemplary Draw String Closure

In the alternate embodiment of FIG. **19**, the device has an opening **74** formed between leaves **26** and **28** which is closable by a string **70** (or other puller) attached to sliding mechanism **72** which is in the form of a zip-lock. More specifically, pulling of the string **70** proximally, which extends outside the patient, pulls the locking (sealing) mechanism proximally to bring together edges **76**, **78** in the same manner as edges **64**, **66** described above. This seals the device to prevent leakage of fluids. Note in all other respects, the device of FIG. **19** is identical to device **10** of FIG. **15**, e.g., leaves **22-28**, projections, distal end cap **44**, expander **50**, etc. so for brevity, further details will not be discussed since the configuration and function of the components of FIG. **15** are fully applicable to the embodiment of FIG. **19**.

The device **10** also includes a proximal base **40** (see e.g., FIG. **11**) forming a flange to engage the trocar or skin of the patient to provide a stop to prevent the entire device **10** slipping into the body cavity. The base **40** has an opening **42** to receive mounting tube **46** which has a flange **48** seated within the base **40** and a tubular portion **49** which extends into the proximal opening of tube **11** of device **10**. A marker **43** has a triangular pointed tip **43***a* to provide a directional marker for the user which can be configured to indicate the direction of the abdominal wall, or the direction of the opening between the leaves, or other direction. Preferably, the device **10** with base **40** and tube **46** are formed integrally (monolithically) as one piece, although it is also contemplated that they can be formed as separate components.

Exemplary Usage of Zipper Device

Turning now to the method of use, and with reference to FIGS. **13-18**, one method of using the device of FIG. **11** is illustrated. Note FIGS. **13-18** shown the device inserted through a trocar into the abdominal cavity, however, alternatively the device can be inserted into other regions of the

body, such as the joint space or pleural cavity, and can alternatively be inserted through a natural body opening instead of through a trocar.

As shown in FIGS. **13** and **14**, device **10** is inserted through a conventional trocar T**1** (shown generically), through the abdominal wall W and into the insufflated abdominal cavity C. The device **10** is inserted in the low profile collapsed position as shown with the tube **11** in a cylindrical configuration to facilitate insertion. The device **10** can be inserted with the expander **50** within the device but out of engagement with the projections or, alternatively, the expander **50** can be inserted after the device **10** is inserted through the trocar as shown in FIG. **14**. After positioning of the device **10** within the abdominal cavity, the tube **11** optionally can be locked in place to restrict axial movement. Next, the expander **50** is advanced distally so that its engaging surface applies a force to the projections **32-38**, forcing the projections **32-38** outwardly to move the tube **11** to the expanded configuration of FIG. **15**, i.e., to separate the leaves **22-28** to form the box-like structure. Next a grasper is inserted through another trocar T**2** (shown generically) to grasp the specimen S and move it through opening **62** in cover **60** for placement in space **27** within tube **11**. The same grasper (or a different grasper **100**) then grips lock **68** (FIG. **17**) and slides it proximally to bring edges **64**, **66** of cover **60** together to seal the space **27** containing the specimen S as shown in FIG. **18**. If the device of FIG. **19** is used, once the specimen is placed within the tube **11** by a grasper, the user pulls string **70** proximally to move the lock **72** to bring edges **74** and **76** together to seal the space **27** containing the specimen S.

Optionally, a morcellator can be inserted through the valve **54** of expander **50** and through the trocar T**1** to access the interior of the tube **11**. The morcellator can be a power morcellator or a non-powered morcellator such as coring tube to break up the specimen into smaller particles to facilitate removal through the laparoscopic port. FIG. **20** illustrates a power morcellator **110** with handle **112** inserted into the device to access the specimen S within space **27** of tube **11**. After morcellation of the specimen S, the morcellator is removed from the body.

At the end of the procedure the expander **50** is removed or retracted from tube **11**, allowing the outer tube **11** to return to the collapsed low profile configuration, e.g., its previous cylindrical shape, as shown in FIG. **21**, and the device **10** can then be removed from the patient's body. The sheets of material covering the gaps between the leaves will also collapse either because of inherent elasticity or because of the pressure gradient between the peritoneal cavity and the inside of the device.

It should be noted that grasper (or other tool) **100** and/or drawstring **70** may also be used to deploy and/or reveal adhesive. Optionally, if a zipper **68** is used to bring edges **64** and **66** together, once they interlock and/or adhere, zipper **68** may be removed.

Exemplary Threaded Rigidifying Member

In the alternate embodiment of FIGS. **22**A-**22**C, the expander **80** has an external screw thread **83** on the tubular portion **82** engageable with an internal screw thread **95** within mounting tubular portion **97** of tube **92**. The expander **80** can be a separate component insertable into tube **92** or alternatively be provided as a unit attached to tube **92**. In use, the expander **80** is rotated to advance it into tube **92** as shown in FIG. **22**B. Upon sufficient advancement, the distal end of tubular portion **82** of expander **80** engages the internal projections of the leaves **22**, **24**, **26** and **28** to force them outwardly as shown in FIG. **22**C.

Exemplary Hinged Workspace Device

In the alternate embodiment of FIGS. **23**A-**23**C, the specimen retrieval device is in the form of a hinged box **100**. Box **100** has hinges **106**, **108** having springs to enable box **100** to spring outwardly when advanced from the trocar T**3**. Additional hinges **102**, **104** and **110**, **112** are provided at the distal and proximal portions and can also have springs. As shown in FIG. **23**A, the box **100** is maintained in the collapsed position by the tubular portion of trocar T**3**. The box **100** is advanced beyond the tubular portion of the trocar T**3** into the body cavity (FIG. **23**B). When sufficiently advanced into the body cavity, it will spring out into the football shaped configuration of FIG. **23**C. After positioning of a specimen therein, the box **100** is retracted through the trocar T**3**, with the wall of the tubular portion of trocar T**3** collapsing the box **100** to its cylindrical shape for withdrawal.

Some Exemplary Potential Advantages of Some Embodiments of the Invention

As can be appreciated, the device of some embodiments of the present invention can, if desired, often be used with a morcellator without at least some of the risks associated with current morcellators for several reasons. First, the device, in some embodiments thereof, creates a protected space (the "box") within the patient's body where tissue particles for removal can be isolated and morcellated without fear of scattering the tissue inside the patient's body. That is, it could allow power morcellation even when the risk of neoplasm cannot be ruled out (fibroids) because the box's walls are kept away from the morcellator and the risk of their rupture is very small. This may be useful inside the uterus.

Second, because the device, in some embodiments thereof, has semi-rigid edges it holds its shape by itself (keeps it in the expanded form) and there is no need for insufflation inside the bag. Insufflation of the body cavity is outside the box and it separates the bowel loops from the walls of the box for added safety. Since the device forms a box with sufficiently rigid walls and not a bag, the walls of the device stay away from the morcellator and are less likely to be cut by it. This not only prevents scattering of tissue but also reduces the chance of injury to the patient's organs.

Additionally, in some exemplary embodiments of the invention, the device maintains the pressure within its space below the pressure inside the peritoneal cavity so that if a hole in its wall occurs the airflow will be from the peritoneal cavity into the box and not the other way so there is no spraying of tissue particles into the peritoneal cavity. As the insufflation is outside the box, there is a pressure gradient between the peritoneal cavity and the inside of the box, i.e., the pressure inside the device is lower than the pressure in the surrounding peritoneal cavity. Therefore, if small holes occur in the cover, then the airflow will go into the box and not outside, i.e., the pressure gradient will hinder the morcellated tissue from spilling outside the device. Moreover, since insufflation goes into the peritoneal cavity, the bowel loops are kept away from the device (box), thereby allowing direct visualization of the device with a laparoscope from outside the box inserted through another port or body opening, while the morcellation of the mass or the drainage of the cyst takes place inside the box that has transparent walls. The scope is placed outside the box to monitor the morcellation through the box's transparent walls.

In some exemplary embodiments of the invention, the device can provide tissue removal in one step which is quicker that tissue removal with a bag.

Note that the device, in some embodiments thereof, can be introduced to the peritoneum through a laparoscopy port or through an opening in the cul-de-sac (colpotomy) or through the vaginal cuff after a laparoscopic hysterectomy.

The device, in some embodiments thereof, can be composed of disposable materials or reusable sterilizable materials.

Note the device, in some embodiments, prevents dissemination of tissue material during power morcellation, however, it can be used also for removal of specimens that need drainage without spillage to the peritoneal cavity (a mucinous ovarian cyst or a dermoid cyst) and whenever a specimen has to be removed from the peritoneal cavity. A potential problem with the art which may be solved by some embodiments of the invention is as follows and relates to a desire to use power morcellation fast and safely.

Several safety issues arose over the years regarding the use of power morcellators including: 1) potential injury to the patient's internal organs including injuries to the small and large bowels, vascular system, kidney, ureter, bladder and diaphragm; 2) possible dissemination of benign tissue such as fibroids, endometriosis and adenomyosis which can lead to "parasitic growth" of the disseminated tissue, peritonitis and abscess formation; 3) possible dissemination of malignant tissue which can cause cancer upstaging and worsen the prognosis (unsuspected endometrial carcinoma could be disseminated in the same manner); and 4) potential disruption of malignant tissue pathologic architecture, which could hinder correct pathologic diagnosis or grading. Due to the risk of the dissemination of unsuspected uterine sarcoma, the FDA issued a safety communication on April 2014 (which was updated on November 2014) recommending against using power morcellation in the majority of women undergoing myomectomy or hysterectomy for uterine fibroids. This has led to a sharp decline in the use of power morcellators in the U.S.

In attempts to prevent the dissemination of morcellated tissue inside the peritoneal cavity, special specimen bags have been used in several techniques. One technique involves placing the specimen in a bag, bringing the free edges of the bag through a laparoscopy port that has been extended (in essence turning the procedure to a minilaparotomy) and morcellating the specimen manually. This has the potential disadvantage of having larger incisions of open surgery and of extending the time of the operation. Another technique is placing the specimen in a bag, bringing the free edges of the bag through a culdotomy (or through the open vagina in case of a total laparoscopic hysterectomy) and manually morcellating the specimen. This has the potential disadvantage of extending the time of the operation.

Another problem relates to where an imaging device is placed for imaging the morecellation. It may be difficult to visualize the morcellation from outside the bag unless another insufflation source is connected to keep the pneumoperitoneum outside the bag. Such a scope can view the morcellation from inside the bag, however, in this technique the integrity of the bag may be compromised and leakage of tissue might occur during the morcellation or when the bag is removed after the morcellation.

There are several potential disadvantages to the use of a bag during morcellation. First, there could be leakage from the bag. The bag could be defective as a result of the manufacturing process or as a result of the manipulation of the bag during the procedure, i.e., due to insertion and removal of the bag, inadvertent laceration by the tenaculum or by the morcellating device. Also, pulling the tissue towards the morcellator can pull with it the bag wall that might be cut inadvertently by the morcellator. Second, in the technique where the bag is insufflated, the pressure inside the bag is higher than the pressure in the surrounding peritoneal cavity. Thus, even a small defect in the bag can lead to spraying of tissue containing fluid (blood, irrigation fluid) to the surrounding environment. Third, the process of setting up the bag for morcellation is time consuming, and in some cases up to twenty minutes could be spent on this step.

It is noted that devices as describe din accordance with some embodiments of the invention can work with a range of different morecellators, including, potentially morecellators with a potential to damage retrieval bags and/or spray tissue. Possibly, even an exposed blade may be used, if restrained in movement by the frame of the device.

General

While the above description contains many specifics, those specifics should not be construed as limitations on the scope of the disclosure, but merely as exemplifications of preferred embodiments thereof. Those skilled in the art will envision many other possible variations that are within the scope and spirit of the disclosure as defined by the claims appended hereto.

In particular, it is noted that the various species of closure systems, sealing systems, rigidifying systems and safety features are intended to be used with embodiments other than the specific ones used to exemplify them. Furthermore, many of the features described herein can be used to improve prior art designs. For example, safety measures may be used with existing retrieval bag designs.

It is expected that during the life of a patent maturing from this application many relevant tissue reduction technologies will be developed and the scope of the term morcellator is intended to include all such new technologies a priori.

As used herein the term "about" refers to ±10%.

The terms "comprises", "comprising", "includes", "including", "having" and their conjugates mean "including but not limited to".

The term "consisting of" means "including and limited to".

The term "consisting essentially of" means that the composition, method or structure may include additional ingredients, steps and/or parts, but only if the additional ingredients, steps and/or parts do not materially alter the basic and novel characteristics of the claimed composition, method or structure.

As used herein, the singular form "a", "an" and "the" include plural references unless the context clearly dictates otherwise. For example, the term "a compound" or "at least one compound" may include a plurality of compounds, including mixtures thereof.

Throughout this application, various embodiments of this invention may be presented in a range format. It should be understood that the description in range format is merely for convenience and brevity and should not be construed as an inflexible limitation on the scope of the invention. Accordingly, the description of a range should be considered to have specifically disclosed all the possible subranges as well as individual numerical values within that range. For example, description of a range such as from 1 to 6 should be considered to have specifically disclosed subranges such as from 1 to 3, from 1 to 4, from 1 to 5, from 2 to 4, from 2 to 6, from 3 to 6 etc., as well as individual numbers within that range, for example, 1, 2, 3, 4, 5, and 6. This applies regardless of the breadth of the range.

Whenever a numerical range is indicated herein, it is meant to include any cited numeral (fractional or integral)

within the indicated range. The phrases "ranging/ranges between" a first indicate number and a second indicate number and "ranging/ranges from" a first indicate number "to" a second indicate number are used herein interchangeably and are meant to include the first and second indicated numbers and all the fractional and integral numerals therebetween.

It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention, which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination or as suitable in any other described embodiment of the invention. Certain features described in the context of various embodiments are not to be considered essential features of those embodiments, unless the embodiment is inoperative without those elements.

Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims.

All publications, patents and patent applications mentioned in this specification are herein incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention. To the extent that section headings are used, they should not be construed as necessarily limiting.

What is claimed is:

1. A method of processing tissue in a laparoscopic manner, comprising:

inserting a workspace device in a collapsed state from outside of a subject's body into an abdominal cavity of said subject, wherein said workspace device comprises an inflatable body having a wall which defines an internal volume of said workspace device and comprises a membrane, a single opening in said membrane to said internal volume, and at least one rigidizer stiff enough to resist an external pressure of at least 5 mmHg above a pressure in said inflatable body when said inflatable body is expanded;

expanding a cross-sectional size of the single opening positioned within the abdominal cavity;

receiving following said expanding, tissue from said abdominal cavity into said internal volume of said workspace device via the single opening;

removing said single opening through said opening to the outside of said subject's body while keeping said at least one rigidizer inside the subject's body, wherein when said single opening is removed to the outside of the subject's body, said internal volume of said workspace device is sealed from said abdominal cavity to prevent leakage of said tissue located within said internal volume into said abdominal cavity;

inserting a laparoscopic tool into said workspace device through said single opening positioned outside said subject's body.

2. The method according to claim **1**, comprising:

processing said tissue in said device by said laparoscopic tool.

3. The method according to claim **1**, wherein said at least one rigidizer comprises at least one inflatable chamber, when said method comprising rigidifying the at least one inflatable chamber.

4. The method according to claim **1**, comprises rigidifying the workspace device using the at least one rigidizer.

5. The method according to claim **4**, wherein the rigidifying occurs after the tissue from said abdominal cavity is received into said workspace dev-ice.

6. The method according to claim **5**, wherein said at least one rigidizer comprises one or more inflatable chambers, and wherein said rigidifying comprises inflating said one or more inflatable chambers.

7. The method according to claim **4**, wherein the rigidifying occurs before or after the single opening is removed to the outside of the subject's body.

8. The method according to claim **1**, comprising inflating the abdominal cavity above atmospheric pressure, and sealing, after the single opening is removed from the body of the subject, said internal volume of said workspace body from said abdominal cavity to maintain a negative pressure differential between said internal volume of said workspace device and the abdominal cavity.

9. The method according to claim **1**, wherein the pressure in said inflatable body is the pressure of said internal volume defined within the workspace device when the workspace device is expanded and rigidified by the rigidizer.

10. The method according to claim **1**, wherein the tissue comprises at least one of the group consisting of a kidney, a uterus, a portion of a GI tract, and a tumor.

11. The method of claim **1**, wherein said removing comprises retracting edges of said single opening to the outside of said subject's body.

12. The method of claim **1**, wherein said inserting comprises inserting said workspace device through an opening in an abdominal wall into said abdominal cavity.

13. The method of claim **1**, wherein said single opening has lips configured to be elastically predisposed to be normally open, and wherein said expanding comprises opening said lips.

14. The method of claim **1**, wherein said wall comprises two or more layers of said membrane.

15. The method of claim **1**, wherein said workspace device comprising at least one sensor configured to indicate if said wall is damaged.

16. The method of claim **15**, wherein said at least one sensor senses a change in pressure in said wall.

17. The method of claim **1**, wherein said workspace device comprising a tool channel contiguous with said single opening and extending from said inflatable body and configured to remain, at least in part, outside of abdominal wall and sized to receive a laparoscopic tool therein when said single opening is removed to the outside of said subject's body.

18. The method of claim **1**, wherein said wall is transparent or includes one or more transparent regions.

19. The method of claim **1**, wherein said inserting comprises inserting said workspace device through a vagina into said abdominal cavity.

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